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10/27/00 JC953 U.S. PTO

UTILITY PATENT APPLICATION TRANSMITTAL
(Small Entity)

(Only for new nonprovisional applications under 37 CFR 1.53(b))

Docket No.
LN.014C4

Total Pages in this Submission

TO THE ASSISTANT COMMISSIONER FOR PATENTS
Box Patent Application
Washington, D.C. 20231

Transmitted herewith for filing under 35 U.S.C. 111(a) and 37 C.F.R. 1.53(b) is a new utility patent application for an invention entitled:

COMPOSITE BONE GRAFT, METHODS OF MAKING AND USING SAME

JC825 U.S. PTO 09/698493 10/27/00

and invented by:

Billy G. Anderson and Lloyd Wolfinbarger, Jr.

If a CONTINUATION APPLICATION, *check appropriate box and supply the requisite information:*

☒ **Continuation** ☐ **Divisional** ☐ **Continuation-in-part (CIP)** of prior application No.: **09/368,263**

Which is a:

☐ **Continuation** ☐ **Divisional** ☐ **Continuation-in-part (CIP)** of prior application No.: _____

Which is a:

☐ **Continuation** ☐ **Divisional** ☐ **Continuation-in-part (CIP)** of prior application No.: _____

Enclosed are:

Application Elements

1. ☐ Filing fee as calculated and transmitted as described below

2. ☒ Specification having **101** pages and including the following:

   a. ☒ Descriptive Title of the Invention

   b. ☒ Cross References to Related Applications *(if applicable)*

   c. ☒ Statement Regarding Federally-sponsored Research/Development *(if applicable)*

   d. ☐ Reference to Microfiche Appendix *(if applicable)*

   e. ☒ Background of the Invention

   f. ☒ Brief Summary of the Invention

   g. ☒ Brief Description of the Drawings *(if drawings filed)*

   h. ☒ Detailed Description

   i. ☒ Claim(s) as Classified Below

   j. ☒ Abstract of the Disclosure

UTILITY PATENT APPLICATION TRANSMITTAL
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Total Pages in this Submission

Application Elements (Continued)

3. ☐ Drawing(s) *(when necessary as prescribed by 35 USC 113)*
   a. ☒ Formal b. ☐ Informal Number of Sheets 22

4. ☒ Oath or Declaration
   a. ☐ Newly executed *(original or copy)* ☐ Unexecuted
   b. ☒ Copy from a prior application (37 CFR 1.63(d)) *(for continuation/divisional application only)*
   c. ☒ With Power of Attorney ☐ Without Power of Attorney
   d. ☐ *DELETION OF INVENTOR(S)*
   Signed statement attached deleting inventor(s) named in the prior application, see 37 C.F.R. 1.63(d)(2) and 1.33(b).

5. ☒ Incorporation By Reference *(usable if Box 4b is checked)*
   The entire disclosure of the prior application, from which a copy of the oath or declaration is supplied under Box 4b, is considered as being part of the disclosure of the accompanying application and is hereby incorporated by reference therein.

6. ☐ Computer Program in Microfiche

7. ☐ Genetic Sequence Submission *(if applicable, all must be included)*
   a. ☐ Paper Copy
   b. ☐ Computer Readable Copy
   c. ☐ Statement Verifying Identical Paper and Computer Readable Copy

Accompanying Application Parts

8. ☒ Assignment Papers *(cover sheet & documents)*

9. ☒ 37 CFR 3.73(b) Statement *(when there is an assignee)*

10. ☐ English Translation Document *(if applicable)*

11. ☐ Information Disclosure Statement/PTO-1449 ☐ Copies of IDS Citations

12. ☒ Preliminary Amendment

13. ☒ Acknowledgment postcard

14. ☒ Certificate of Mailing
   ☐ First Class ☒ Express Mail *(Specify Label No.):* **EK593738789US**

UTILITY PATENT APPLICATION TRANSMITTAL
(Small Entity)

(Only for new nonprovisional applications under 37 CFR 1.53(b))

Docket No.
LN.014C4

Total Pages in this Submission

Accompanying Application Parts (Continued)

15. ☐ Certified Copy of Priority Document(s) *(if foreign priority is claimed)*

16. ☒ Small Entity Statement(s) - Specify Number of Statements Submitted: **one**

17. ☐ Additional Enclosures *(please identify below):*

Fee Calculation and Transmittal

CLAIMS AS FILED

For	#Filed	#Allowed	#Extra	Rate	Fee
Total Claims	51	- 20 =	31	x $9.00	$279.00
Indep. Claims	7	- 3 =	4	x $39.00	$156.00
Multiple Dependent Claims (check if applicable) ☒					$130.00
				BASIC FEE	$345.00
OTHER FEE *(specify purpose)*					$0.00
				TOTAL FILING FEE	$910.00

☐ A check in the amount of to cover the filing fee is enclosed.

☐ The Commissioner is hereby authorized to charge and credit Deposit Account No. as described below. A duplicate copy of this sheet is enclosed.

- ☐ Charge the amount of as filing fee.
- ☐ Credit any overpayment.
- ☐ Charge any additional filing fees required under 37 C.F.R. 1.16 and 1.17.
- ☐ Charge the issue fee set in 37 C.F.R. 1.18 at the mailing of the Notice of Allowance, pursuant to 37 C.F.R. 1.311(b).

Dated: **October 27, 2000**

Signature

Susanne M. Hopkins, Esq.
Reg. No: 33,247
LIFENET
7101 Bloomsbury Lane
Spotsylvania, VA 22553
Phone: (540) 834-0000
Fax: (540) 710-9377

cc:

VERIFIED STATEMENT (DECLARATION) CLAIMING SMALL ENTITY STATUS (37 CFR 1.9(f) AND 1.27 (d)) - NONPROFIT ORGANIZATION	Docket No. LN.014C4

Serial No.	Filing Date	Patent No.	Issue Date
To be assigned	October 27, 2000	N/A	N/A

Applicant/ Patentee: **Billy G. Anderson and Lloyd Wolfinbarger, Jr.**

Invention: **COMPOSITE BONE GRAFT, METHODS OF MAKING AND USING SAME**

I hereby declare that I am an official empowered to act on behalf of the nonprofit organization identified below:

NAME OF ORGANIZATION: **LIFENET**

ADDRESS OF ORGANIZATION: **5809 Ward Court**
Virginia Beach, VA 23455

TYPE OF NONPROFIT ORGANIZATION:

- ☐ University or other Institute of Higher Education
- ☐ Tax Exempt under Internal Revenue Service Code (26 U.S.C. 501(a) and 501(c)(3))
- ☐ Nonprofit Scientific or Educational under Statute of State of The United States of America
  Name of State: Citation of Statute:
- ☐ Would Qualify as Tax Exempt under Internal Revenue Service Code (26 U.S.C. 501(a) and 501(c)(3)) if Located in The United States of America
- ☒ Would Qualify as Nonprofit Scientific or Educational under Statute of State of The United States of America if Located in The United States of America
  Name of State: **Virginia** Citation of Statute:

I hereby declare that the above-identified nonprofit organization qualifies as a nonprofit organization as defined in 37 C.F.R. 1.9(e) for purposes of paying reduced fees to the United States Patent and Trademark Office regarding the invention described in:

- ☒ the specification to be filed herewith.
- ☐ the application identified above.
- ☐ the patent identified above.

I hereby declare that rights under contract or law have been conveyed to and remain with the nonprofit organization with regard to the above identified invention.

If the rights held by the above-identified nonprofit organization are not exclusive, each individual, concern or organization having rights to the invention is listed on the next page and no rights to the invention are held by any person, other than the inventor, who could not qualify as an independent inventor under 37 CFR 1.9(c) or by any concern which would not qualify as a small business concern under 37 CFR 1.9(d) or a nonprofit organization under 37 CFR 1.9(e).

Each person, concern or organization to which I have assigned, granted, conveyed, or licensed or am under an obligation under contract or law to assign, grant, convey, or license any rights in the invention is listed below:

- ☒ no such person, concern or organization exists.
- ☐ each such person, concern or organization is listed below.

FULL NAME _____
ADDRESS _____

☐ Individual ☐ Small Business Concern ☐ Nonprofit Organization

FULL NAME _____
ADDRESS _____

☐ Individual ☐ Small Business Concern ☐ Nonprofit Organization

FULL NAME _____
ADDRESS _____

☐ Individual ☐ Small Business Concern ☐ Nonprofit Organization

FULL NAME _____
ADDRESS _____

☐ Individual ☐ Small Business Concern ☐ Nonprofit Organization

Separate verified statements are required from each named person, concern or organization having rights to the invention averring to their status as small entities. (37 CFR 1.27)

I acknowledge the duty to file, in this application or patent, notification of any change in status resulting in loss of entitlement to small entity status prior to paying, or at the time of paying, the earliest of the issue fee or any maintenance fee due after the date on which status as a small entity is no longer appropriate. (37 CFR 1.28(b))

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application, any patent issuing thereon, or any patent to which this verified statement is directed.

NAME OF PERSON SIGNING: **Susanne M. Hopkins, Esq.**

TITLE IN ORGANIZATION: **General Counsel**

ADDRESS OF PERSON SIGNING: **LIFENET**
5809 Ward Court
Virginia Beach, VA 23455

SIGNATURE: _____ DATE: **October 27, 2000**

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Anderson, Billy, et al.	Art Unit: To be assigned
Appl. No.: To be assigned	Examiner: To be assigned
Filed: October 27, 2000	Atty. Docket: LN.014C4

For: **Composite Bone Graft, Method of Making and Using Same**

PRELIMINARY AMENDMENT

The Assistant Commissioner of
Patents and Trademarks
Washington, D.C. 20231

Dear Sir:

Prior to Examination on the merits, please amend the applications as follows. Also, please consider the remarks set forth below, responsive to the Office Action dated 8/24/2000 issued in the parent application U.S patent application serial no: 09/368,263 of the above-identified continuation application.

In the Specification:

Please amend the specification as follows:

Page 10, lines 16 and 19, delete "accomadate" and insert – – accommodate– –.

Page 22, line 19, delete "of".

Page 29, line 2, delete "a".

Page 33, line 10, delete "include" and insert – – includes– –.

Page 35, line 9, delete "groves" and insert – – grooves– –.

In the Claims:

Please delete claims 1-109, without prejudice or disclaimer, and add new claims 110-139.

– – 110. A composite bone graft, comprising:

a first substantially planer cortical bone portion;

a second substantially planer cortical bone portion provided on said first substantially planer cortical bone portion to form a graft unit; and

one or more bone pins for holding together said graft unit, said one or more bone pins are provided perpendicular to or parallel to an interface of said first substantially planer cortical bone portion and said second substantially planer cortical bone portion, wherein said composite bone graft does not comprise an adhesive.

111. A composite bone graft, consisting essentially of:

a first substantially planer cortical bone portion;

a second substantially planer cortical bone portion provided on said first substantially planer cortical bone portion to form a graft unit; and

one or more bone pins for holding together said graft unit, said one or more bone pins are provided perpendicular to or parallel to an interface of said first substantially planer cortical bone portion and said second substantially planer cortical bone portion.

112. A composite bone graft, comprising: two or more distinct, adjacent, cortical bone portions, said distinct, adjacent, cortical bone portions each comprising a face complimentary to a face on an adjacent cortical bone portion, each face comprising a single projection or a single depression, such that adjacent faces are complimentary, and a single projection interlocks with a single depression, to provide an interlocking fit between said adjacent bone portions, wherein said composite bone graft does not comprise an adhesive.

113. A composite bone graft, consisting essentially of: two or more distinct, adjacent, cortical bone portions, said distinct, adjacent, cortical bone portions each comprising a face complimentary to a face on an adjacent cortical bone portion, each face comprising a single projection or a single depression, such that adjacent faces are complimentary, and a single projection interlocks with a single depression, to provide an interlocking fit between said

adjacent bone portions; and one or more locking pins comprising cortical bone, partially or entirely traversing a dimension of said composite bone graft, said one or more locking pins provided perpendicular to or parallel to an interface between adjacent bone portions.

114. A composite bone graft, comprising: two or more distinct, adjacent, cortical bone portions, said distinct, adjacent, cortical bone portions each comprising a face complimentary to a face on an adjacent cortical bone portion, each face comprising a single projection or a single depression, such that adjacent faces are complimentary, and a single projection interlocks with a single depression, to provide an interlocking fit between said adjacent bone portions; and one or more locking pins comprising cortical bone, partially or entirely traversing a dimension of said composite bone graft, said one or more locking pins provided perpendicular to or parallel to an interface between adjacent bone portions, wherein said composite bone graft does not comprise an adhesive.

115. A composite bone graft comprising two or more distinct, adjacent, cortical bone portions layered to form a graft unit; one or more bone pins provided perpendicular to an interface between adjacent bone portions; and a first chamfered edge and a second chamfered edge, said first chamfered edge provided along a length of said composite bone graft at its top edge, and said second chamfered edge provided along a length of said composite bone graft at its bottom edge, such that the chamfered edges are diametrically opposed, wherein said composite bone graft does not comprise an adhesive.

116. The composite bone graft of any one of claims 110 or 111 said first substantially planer cortical bone portion comprises one or more cortical bone planks, and said second substantially planer cortical bone portion comprises one or more cortical bone planks.

117. A composite bone graft, comprising:

a first cortical bone portion;

a second cortical bone portion provided on said first cortical bone portion to form a graft unit; and

one or more bone pins for holding together said graft unit, said one or more bone pins are provided perpendicular to or parallel to an interface of said first cortical bone portion and said second cortical bone portion, wherein said composite bone graft does not comprise an adhesive.

118. The composite bone graft of claim 117, said first cortical bone portion comprises one or more cortical bone planks, and said second cortical bone portion comprises one or more cortical bone planks.

119. The composite bone graft of claim 118, said first cortical bone portion comprises a first face comprising a single protrusion and said second cortical bone portion comprises a second face comprising a single depression complimentary to said first face, such that said first face and said second face interlock.

120. The composite bone graft of any one of claims 110-115, 117-118, or 119, said composite bone graft further comprising a first top surface and a second bottom surface, said first top surface and said second bottom surface comprising a plurality of continuous linear protrusions defining a saw-tooth pattern.

121. The composite bone graft of any one of claims 116, said composite bone graft further comprising a first top surface and a second bottom surface, said first top surface and said second bottom surface comprising a plurality of continuous linear protrusions defining a saw-tooth pattern.

122. The composite bone graft of any one of claims 110 or 111, said composite bone graft is a composite trapezoid wedge, said composite trapezoid wedge, comprising:

a top textured surface;

a bottom textured surface;

an anterior height of from about 3.0 mm to about 30.0mm;

a posterior height of from about 5.0 mm to about 50.0 mm;

a composite width of from about 4.0 mm to about 20.0 mm; and

a length of from about 5.0 mm to about 50.0 mm, wherein said top textured surface and said bottom textured surface are opposing and are disposed perpendicular to interfaces of said bone portions, said top textured surface and said bottom textured surface comprises a plurality of continuous linear protrusions defining a saw-tooth pattern.

123. The composite bone graft of any one of claims 110 or 111, said composite bone graft is a composite parallel block, said composite parallel block comprising:

a top textured surface;

a bottom textured surface;

a height of from about 3.0 mm to about 30.0 mm;

a composite width of from about 4.0 mm to about 20.0 mm; and

a length of from about 5.0 mm to about 50.0 mm, wherein said top textured surface and said bottom textured surface are opposing and are disposed perpendicular to interfaces of said bone portions, said top textured surface and said bottom textured surface comprises a plurality of continuous linear protrusions defining a saw-tooth pattern.

124. The composite bone graft of claim 110, said composite bone graft is a composite cervical wedge, said composite cervical wedge comprising:

a top textured surface;

a bottom textured surface;

a first width of from about 10.0 mm to about 24.0mm;

a second width of from about 4.0 mm to about 16.0 mm;

a composite anterior height of from about 3.0 mm to about 30.0 mm;

a composite posterior height of from about 5.0 mm to about 50.0 mm; and

a diameter of from about 10.0 mm to about 20.0 mm, wherein said top textured surface and said bottom textured surface are opposing and are disposed parallel to interfaces of said bone portions, said top textured surface and said bottom textured surface comprises a plurality of continuous linear protrusions defining a saw-tooth pattern.

125. The composite bone graft of claim 110, said composite bone graft is a composite cervical block, said composite cervical block comprising:

a top textured surface;

a bottom textured surface;

a first width of from about 10.0 mm to about 24.0mm;

a second width of from about 4.0 mm to about 16.0 mm;

a composite height of from about 3.0 mm to about 30.0 mm; and

a diameter of from about 10.0 mm to about 20.0 mm, wherein said top textured surface and said bottom textured surface are opposing and are disposed parallel to interfaces of said bone portions, said top textured surface and said bottom textured surface comprises a plurality of continuous linear protrusions defining a saw-tooth pattern.

126. The composite bone graft of any one of claims 123 or 125, further comprising a through-hole entirely traversing said composite bone graft and disposed substantially perpendicular to interfaces of said bone portions.

127. The composite bone graft of claim 126, said through-hole comprising a cross-section having a shape selected from the group consisting of: substantially round; substantially elliptical; and substantially oval.

128. The composite bone graft of claim 112, further comprising one or more bone pins.

129. The composite bone graft of claim 128, one or more bone pins comprise one or more cortical bone pins.

130. The composite bone graft of claim 129, said one or more cortical bone pins are located perpendicular to interfaces of adjacent bone portions, and entirely traverses said composite bone graft.

131. The composite bone graft of claim 130, said one or more cortical bone pins comprise locking pins located parallel to interfaces of adjacent bone portions, where one locking pin is provided at each interface of adjacent bone portions parallel to that interface, said locking pins partially traverse said composite bone graft.

132. The composite bone graft of any one of claims 110 or 111, said bone portions comprise allogenic or xenogenic bone.

133. The composite bone graft of any one of claims 110-115, or 117, said composite bone graft further comprising a top surface; a bottom surface; a diameter of from about 10.0 mm to about 20.0 mm; a width of from about 12.0 mm to about 25.0 mm; an anterior composite height of from about 5.0 mm to about 10.0 mm; and a posterior composite height of from about 5.0 mm to about 15.0 mm.

134. The composite bone graft of claim 133, said top surface and said bottom surface comprising a plurality of continuous linear protrusions defining a saw-tooth pattern.

135. The composite bone graft of any one of claims 121, 124, or 125, said continuous linear protrusions comprise a height of from about 0.1 mm to about 5.0 mm.

136. The composite bone graft of claim 120, said plurality of continuous protrusions having a height of from about 0.1 mm to about 5.0 mm.

137. The composite bone graft of claim 122, said plurality of continuous protrusions having a height of from about 0.1 mm to about 5.0 mm.

138. The composite bone graft of claim 123 said plurality of continuous protrusions having a height of from about 0.1 mm to about 5.0 mm.

139. The composite bone graft of claim 134 said plurality of continuous protrusions having a height of from about 0.1 mm to about 5.0 mm.– –

REMARKS

Claims 110-139, are pending in the present application. Claims 1-109 have been cancelled without prejudice or disclaimer. New claims 110-139 have been added. Support for these claims appears throughout the specification, drawings, and claims as originally filed. No new matter has been added.

I. At page 2 of the Office Action, the Examiner rejects several claims under 35 USC §112, second paragraph, as being indefinite.

These claims are not pending in the above-identified application. Accordingly this rejection is rendered moot.

II. At page 2 of the Office Action, claims 161 and 162, have been rejected under 35 USC §102, as being anticipated by Boyce.

There are no claims pending which correspond to claims 161 and 162. Accordingly, this rejection is rendered moot.

III. At page 3 of the Office Action, the Examiner rejects claims 110, 111, 120-122, 124, 125, 130-133, 147, 152/124, 152/125, 152/132, 152/133, and 163 under 35 USC §103,as being unpatentable over Boyce in view of McIntyre.

Claims 1-109 have been cancelled without prejudice or disclaimer. New claims 110-139 have been added. None of new claims 110-139 correspond to the rejected claims. Accordingly, this rejection is rendered moot.

IV. At page 5 of the Office Action, claims 126, 137/126, 144-146, and 152/126, have been rejected under 35 USC §103 as being unpatentable over Boyce et al. in view of Burkhead et al.

Claims 1-109 have been cancelled without prejudice or disclaimer. New claims 110-139 have been added. Claims 112-114, 120, and 133, 134, and139 are directed to bone implants including adjacent, cortical bone portions with the complimentary faces on adjacent cortical bone portions including a single projection or a single depression, where the composite bone graft does not include an adhesive.

The Examiner states that Boyce et al. teach a bone-derived implant including alternating layers of cortical bone demineralized to different degrees. The sources of the bone are preferably allogenic but may also include xenogenic sources. The Examiner states that the layers are bound together mechanically or with biocompatible adhesives. The Examiner concludes that Boyce et al. teach all of the limitations of the present invention except that adjacent bone portions comprise complementary peg-like protrusions and corresponding depressions. The Examiner states that Burkhead et al. teach a glenoid prosthesis including pegs which engage gap holes to hold the lateral component of the prosthesis to the head of the scapula. The Examiner concludes that it would have been obvious to one of ordinary skill in the art to have formed pegs which are integral with the adjacent bone portions of Boyce et al. and corresponding depressions as taught by Burkhead et al. so as to avoid the complication of additional parts during implantation. Lastly, the Examiner states that dimensioning is considered to be an obvious choice or design. In view of the following, this rejection is respectively traversed.

Boyce discloses a bone-derived implant made up of one or more layers of fully mineralized or partially demineralized cortical bone and optionally one or more layers of some other material as recited in Boyce at col. 4, lines 24-33. Boyce et al. do not teach or suggest a bone implant held together by a single projection and an single depression on adjacent cortical bone sections to provide an interlocking fit.

Burkhead et al. are directed to a glenoid prosthesis composed of polyethylene and including a pair of pegs extending from a flat medial surface where the pegs are positioned in a pair of holes drilled in a flat resected surface on the scapula head. In a first embodiment, Burkhead et al. *require* at least a pair of pegs and claim 1 recites "a plurality" of "posts." See col. 3, line 10, the Abstract and claim 1.

In a second embodiment, Burkhead et al. discloses a metal backed glenoid prosthesis including a plastic insert having a lateral articulating surface for interacting with the humeral head, a flat medial surface having an indented edge which forms a raised medial portion, and a pair of snap fit, outwardly projecting, L-shaped protrusions. Col. 3, paragraph 5, discloses an embodiment where "...receives a bone screw for fixation to the bone. In addition, one or more posts or auxiliary screws are provided around the perimeter of the base to further stabilize the base against rocking and to prevent rotation of the base on the bone..."

it is submitted that the Examiner has not established a proper case of *prima facia* obviousness. A proper case of *prima facia* obviousness under 35 U.S.C. § 103, requires that the prior art as a whole, must suggest the desirability of making the claimed combination and provide a reasonable expectation of success. Obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art.

In the present case, Burkhead et al. do not suggest a bone implant having adjacent bone portions where the bone portions have a single complimentary protrusion and depression so as to provide an interlocking fit between the bone portions, as presently claimed. In fact, Burkhead et al. *teach away* from such an implant.

As discussed previously, the law on *teaching away* is clear and must be considered. Again, the court in ***In re Dow Chemical Co.,*** 837 F.2d 469, 5 USPQ2d 1529 (Fed. Cir. 1988) held in reference to obviousness, that: "...In determining whether such a suggestion can fairly be gleaned

from the prior art, the full field of the invention must be considered for the person of ordinary skill is charged with the knowledge of the ...including that which might lead away from the claimed invention." The court in ***In re Gurley,*** 27 F.3d 551, 31 USPQ2d 1130 (Fed. Cir. 1994) held that "A prior art reference may be said to *teach away* when a person of ordinary skill; upon reading the reference, would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path that was taken by the applicant." The court in ***Bausch & Lomb, Inc. v. Barnes-Hind/Hydrocurve, Inc.,*** 796 F.2d 443, 230 USPQ 416 (Fed. Cir. 1986), held that "A reference should be considered as a whole, and portions arguing against or teaching away from the claimed invention must be considered.

Burkhead et al. *teach away* from an implant having as single projection, as presently claimed, because Burkhead et al. teaches that at least two pegs are required to "stabilize" and to "prevent rotation." Col. 3, lines 20-23 states: "...at least two spaced pegs are provided so that the component resists rotational loading. The spaced pegs also minimize the effect of superior-inferior loading and anterior-posterior loading."

Neither of the references suggest an implant having as single projection, as presently claimed. In fact, Burkhead et al. *teach away* from such an implant. Thus, in view of this "*teaching away*" the references do not provide any "teaching, suggestion, or motivation" to "combine or modify" their teachings to arrive at the claimed invention.

Assuming *arguendo,* that some teaching, motivation, or suggestion, did exist, at most, the Examiner has only established that it would be "obvious to try," because there is no reasonable expectation of success. There is no reasonable expectation of success because none of the references taken alone or together teach or suggest that bone material could be expected to behave similar to the synthetic material of Burkhead et al. Burkhead et al. do not suggest, for example, that bone posses mechanical properties similar to those of Burkhead et al., or that bone material could achieve the desired result.

In view of the references, it is submitted that one of ordinary skill in the art would not be motivated to even investigate a bone implant including adjacent cortical bone portions having complimentary faces, each of which includes a single depression or protrusion to provide an interlocking fit between bone portions. In fact, one or ordinary skill in the art would be led away from doing so by the teachings of the references, and that even if such investigation were undertaken, there would be no expectation of success since bone material and synthetic materials are vastly different and exhibit vastly different properties including mechanical properties.

In view of the above, it is submitted that the Examiner has not established a proper case of *prima facie obviousness*. Further, it is submitted that nothing in either Boyce et al. or Burkhead et al., taken alone or together, render the claimed invention obvious within the meaning of 35 USC §103. Accordingly, the Examiner is respectfully requested to withdraw this rejection.

V. At page 6 of the Office Action, claims 127, 128, 152/127, and 152/128, have been rejected under 35 USC §103 as being unpatentable over Boyce et al. and McIntyre.

Claims 1-109 have been cancelled without prejudice or disclaimer. New claims 110-139 have been added. None of new claims 110-139 correspond to the rejected claims. Accordingly, this rejection is rendered moot.

VI. At page 8 of the Office Action, claims 134, 135, 136, and 152/134, have been rejected under 35 USC §103 as being unpatentable over Boyce et al. and McIntyre as applied to claims 132 and 133 above and further in view of the following: the inclusion of both interlocking bone portions and locking pins would have been obvious as additional assurance that the multiple bone portions would remain fastened together.

Claims 1-109 have been cancelled without prejudice or disclaimer. New claims 110-139 have been added. None of new claims 110-139 correspond to the rejected claims. Accordingly, this rejection is rendered moot.

VII. At page 8 of the Office Action, claims 164-166, have been rejected under 35 USC §103 as being unpatentable over Boyce et al. and McIntyre.

Claims 1-109 have been cancelled without prejudice or disclaimer. New claims 110-139 have been added. None of new claims 110-139 correspond to the rejected claims. Accordingly, this rejection is rendered moot.

VIII. At page 10 of the Office Action, claims 137/124, 125, 127, 128, 132, 133, 134; and 158/137/124, 125, 127, 128, 132, 133, and 134, have been rejected under 35 USC §103 as being unpatentable over Boyce et al. in view of McIntyre and Coates et al.

Claims 1-109 have been cancelled without prejudice or disclaimer. New claims 110-139 have been added. None of new claims 110-139 correspond to the rejected claims. Accordingly, this rejection is rendered moot.

IX. At page 11 of the Office Action, claims 155/127 and 155/128 have been rejected under 35 USC §103 as being unpatentable over Boyce et al. and McIntyre as applied to claims 127 and 128 above, and further in view of the following considerations concerning the dimensional/shape limitations: Boyce et al. teach that different shapes may be used for different applications.

Claims 1-109 have been cancelled without prejudice or disclaimer. New claims 110-139 have been added. None of new claims 110-139 correspond to the rejected claims. Accordingly, this rejection is rendered moot.

X. At page 12 of the Office Action, claims 156/155/127 and 156/155/128 have been rejected under 35 USC §103 as being unpatentable over Boyce et al. and McIntyre as applied to claims 155/127 and 155/128 above, and further in view of Coates et al.

Claims 1-109 have been cancelled without prejudice or disclaimer. New claims 110-139 have been added. None of new claims 110-139 correspond to the rejected claims. Accordingly, this rejection is rendered moot.

It is submitted that claims 110–139 are in condition for immediate allowance and early notice to that effect is respectfully requested. The Examiner is invited to contact the undersigned at her Spotsylvania, Virginia telephone number on any questions that may arise.

Respectfully submitted,
LIFENET

Susanne M. Hopkins
Attorney for Applicant
Registration no: 33,247

Date: October 27, 2000
LIFENET
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COMPOSITE BONE GRAFT, METHOD OF MAKING AND USING SAME

This application is a Continuation-in-Part application of United States Patent Application Serial No: 09/286,975, filed April 6, 1999, which is a Continuation-in-Part of United States Patent Application Serial No: 09/225,299, filed January 5, 1999, now pending.

FIELD OF THE INVENTION

The invention relates to bone grafts and more particularly, to bone grafts useful for spinal fusion. The invention provides a composite bone graft for implantation in a patient, and methods of making and using the composite bone graft. The composite bone graft contains two or more distinct bone portions where the bone portions are connected. The bone portions are preferably self-locking, interlocking, and/or connected by at least one mechanical connector, including for example, a bone pin. One or more of the bone portions may be demineralized, and may also be continuous or discontinuous. The composite bone graft may include one or more textured surfaces, preferably including a plurality of closely spaced protrusions. The composite bone graft is useful for repairing bone defects caused by congenital anomaly, disease, or trauma, and is particularly useful for spinal fusions. The composite bone graft can be appropriately sized for any application and can be used to replace traditional non-bone prosthetic implants. The composite bone graft promotes the growth of patient bone at an implantation site by promoting osteoinductivity and cellularization, provides added stability and mechanical strength, and does not shift, extrude or rotate, after implantation.

BACKGROUND OF THE INVENTION

In the field of prosthetic implants, materials often used include bone grafts and implants produced from non-bone materials, including for example stainless steel, titanium and plastics. The

choice of whether to use a bone or a non-bone implant often depends on the clinical indication, implant site, whether the implant is load-bearing, and the size of the implant needed.

Prior to the present invention, the use of bone grafts versus non-bone prosthetic implants to for example, support and fuse together adjacent vertebrae, has been limited in part by the physical size of a cortical bone graft. Interbody bone grafting involves the problem of strength. Strong cortical bone (the outer layer) is required as a strut in the interbody position to prevent collapse of the disc space while healing occurs. For example, cortical bone obtained from a cadaver source fashioned into struts, is not wide enough for optimum load bearing. This natural limitation often excludes the use of a bone graft product.

The success or failure of a bone graft further depends on whether the bone graft remains at the implant site, is cellularized, and whether it can withstand the mechanical load. In spinal surgery, there are two primary indications for use of allograft bone: (1) when there is insufficient available autograft bone, and (2) in spinal fusion procedures when a structural element in needed. Typically, bone grafts are affixed at an implant site by fusion. Bone grafts for spinal applications often fail because they are extruded from the implantation site due to shifting, rotation, and slippage of the graft, are not cellularized, or fail mechanically.

The invention enables the use of bone grafts for applications normally suited for only non-bone prosthetic implants. The invention solves the problem of graft failure by providing a composite bone graft which can be appropriately sized for any application out of for example, strong cortical bone; promotes the ingrowth of patient bone at an implantation site by promoting osteoinductivity and cellularization; provides added stability and mechanical strength; and does not shift, extrude or rotate; after implantation.

SUMMARY OF THE INVENTION

The present invention is directed to a composite bone graft for repairing bone defects caused by congenital anomaly, disease, or trauma, including for example, for restoring vertical support of the posterior and/or anterior column. The present composite bone grafts can be used as structural grafts placed posteriorly in the spine as interbody grafts or as strut grafts spanning multiple segments. Posterior composite bone grafts can be used to supplement autologous bone for spinal fusions in patients who lack sufficient host bone and to avoid significant donor site morbidity. The present composite bone grafts can be used for applications normally suited for only non-bone prosthetic implants because the composite bone graft can be appropriately sized for any application and has adequate mechanical strength.

The invention provides a composite bone graft including a plurality of bone portions layered to form a graft unit, and one or more biocompatible connectors for holding together the graft unit.

The invention also provides a composite bone graft including two or more distinct bone portions, and one or more biocompatible connectors, where the biocompatible connectors hold together the two or more bone portions to form the composite bone graft.

The present invention provides a composite bone graft including two or more connected, distinct bone portions.

The present invention provides a composite bone graft including three or more connected, distinct bone portions.

The present invention provides a composite bone graft including three or more connected, distinct cortical bone portions.

The present invention provides a composite bone graft including one or more horizontally disposed channels provided through the composite bone graft perpendicular to the interfaces of the bone portions.

The present invention also provides a composite bone graft including one or more vertically disposed channels provided through the composite bone graft parallel to the interfaces of the bone portions.

The present invention further provides a composite bone graft including one or more horizontally disposed channels and vertically disposed channels where the one or more channels includes one or more therapeutically beneficial substances.

The invention further provides a composite bone graft including two or more connected bone portions, where the bone portions can include cortical bone and cancellous bone.

The invention also provides a composite bone graft, including a first bone portion, a second bone portion, a third bone portion, the first, second and third bone portions are disposed one on the other (ie. layered) to form a graft unit; and one or more biocompatible connectors for holding together the graft unit.

The invention provides a composite bone graft, including a first cortical bone portion, a second cortical bone portion, a cancellous bone portion disposed between the first cortical bone portion and the second cortical bone portion to form a graft unit, and one or more biocompatible connectors for holding together the graft unit.

The invention further provides a composite bone graft, including a first cortical bone portion, a second cortical bone portion provided on the first cortical bone portion to form a graft unit; and one or more biocompatible connectors for holding together the graft unit.

The invention provides a composite bone graft, including a plurality of layered cortical bone portions forming a graft unit, and one or more biocompatible connectors for holding together the graft unit.

The invention provides a composite bone graft, including a plurality of layered bone portions forming a graft unit, and one or more biocompatible connectors for holding together the graft unit.

The invention also provides a composite bone graft, including a first bone portion, a second bone portion provided on the first bone portion to form a graft unit, and one or more biocompatible connectors for holding together the graft unit.

The invention provides a composite bone graft including a plurality of distinct bone portions, where one or more of the bone portions are demineralized.

The invention provides a composite bone graft including a plurality of distinct bone portions, where one or more of the bone portions are continuous or discontinuous.

The invention further provides a composite bone graft including a plurality of distinct bone portions where one or more of the bone portions include a discontinuous bone portion, the discontinuous bone portion including one or more therapeutically beneficial substances including but not limited to, for example, one or more of the following: osteoinductive substances, osteoconductive substances, and pharmaceutically active agents. Such therapeutically beneficial substances may optionally be provided with a carrier. Suitable osteoinductive substances include but are not limited to, for example, autograft bone; allograft bone; Grafton™ produced by Osteotech; DynaGraft™; demineralized cortical bone; demineralized cancellous bone; collagen including one or more growth factors including for example Novus™ produced by Stryker Biotech; collagen including demineralized bone including for example DynaGraft™; cancellous bone; cortical bone;

OpteoForm™ produced by the University of Florida; OsteoFill™ produced by the University of Florida; and growth factors including for example, bone morphogenic protein, and transforming growth factor-β. Suitable osteoconductive substances include but are not limited to, for example, hydroxyapitate; collagen; any biocompatible matrix material including for example, polymeric matrix materials, bioglass, bioceramics, resorbable Biomaterials; bioabsorbable polymers; a plastic matrix; stainless steel; titanium; cobalt-chromium-molybdenum alloy matrix; and substances including hydroxyapitate, including for example, Osteoset™ produced by Wright Medical. Suitable pharmaceutically active agents include but are not limited to, for example, growth factors including for example bone growth factors including for example bone morphogenic protein, and transforming growth factor-β, chemotherapeutic agents, anti-inflammatory agents, and antibiotics.

The invention also provides a composite bone graft, including a first cortical bone portion, a second cortical bone portion, a cancellous bone portion disposed between the first cortical bone portion and the second cortical bone portion to form a graft unit, and one or more biocompatible connectors for holding together the graft unit, where the cancellous bone portion is demineralized and discontinuous.

The invention provides a composite bone graft, including a first cortical bone portion, a second cortical bone portion, and a third cortical bone portion disposed between the first cortical bone portion and the second cortical bone portion to form a graft unit, and one or more biocompatible connectors for holding together the graft unit, where the third cortical bone portion is demineralized and discontinuous.

The invention provides a composite bone graft, including a first cortical bone portion, and a second cortical bone portion disposed apart from each other, and forming a graft unit, and one or

more biocompatible mechanical connectors for holding together the graft unit, where the first and second cortical bone portions are disposed separate from each other by the biocompatible mechanical connectors, thereby forming a substantially void central area.

The invention further provides a composite bone graft including a substantially void central area, where the substantially void central area further includes one or more therapeutically beneficial substances including but not limited to, for example, one or more of the following: osteoinductive substances, osteoconductive substances, and pharmaceutically active agents. Such therapeutically beneficial substances may optionally be provided with a carrier. Suitable osteoinductive substances include but are not limited to, for example, autograft bone; allograft bone; Grafton™ produced by Osteotech; DynaGraft™; demineralized cortical bone; demineralized cancellous bone; collagen including one or more growth factors including for example Novus™ produced by Stryker Biotech; collagen including demineralized bone including for example DynaGraft™; cancellous bone; cortical bone; OpteoForm™ produced by the University of Florida; OsteoFill™ produced by the University of Florida; and growth factors including for example bone morphogenic protein, and transforming growth factor-β. Suitable osteoconductive substances include but are not limited to, for example, hydroxyapitate; collagen; any biocompatible matrix material including for example, polymeric matrix materials, bioglass, bioceramics, resorbable Biomaterials; bioabsorbable polymers; a plastic matrix; stainless steel; titanium; cobalt-chromium-molybdenum alloy matrix; and substances including hydroxyapitate, including for example, Osteoset™ produced by Wright Medical. Suitable pharmaceutically active agents include but are not limited to, for example, growth factors including for example bone growth factors including for example bone morphogenic protein, and transforming growth factor-β; chemotherapeutic agents; anti-inflammatory agents; and antibiotics. The material

may be in any suitable form including for example, in the form of a solid, sponge, paste, powder, and/or gel.

The invention further provides a composite bone graft where the biocompatible connectors include one or more mechanical biocompatible connectors.

The invention provides a composite bone graft where the biocompatible connectors include a chemical biocompatible connector.

The invention further provides a composite bone graft where the mechanical biocompatible connectors include one or more pins.

The invention further provides a composite bone graft where the chemical biocompatible connectors include a biocompatible adhesive.

The invention provides a composite bone graft where one or more biocompatible connectors include one or more of the following: a mechanical connector and a chemical connector.

The invention also provides a composite bone graft where the mechanical biocompatible connectors include one or more of the following biocompatible materials: cortical bone; stainless steel; titanium; cobalt-chromium-molybdenum alloy; a bioceramic; a bioglass; a plastic of one or more of the following: nylon, polycarbonate, polypropylene, polyacetal, polyethylene, and polysulfone; and one or more bioabsorbable polymers.

The invention also provides a composite bone graft where the mechanical biocompatible connectors include cortical bone.

The invention provides a composite bone graft where the one or more pins include one or more cortical bone pins.

The invention provides a composite bone graft where the graft unit includes one or more through-holes configured to accomadate the one or more pins.

The invention further provides a composite bone graft where the through-holes are disposed perpendicular to interfaces of bone portions forming the graft unit.

The invention further provides a composite bone graft where the through-holes are disposed perpendicular to interfaces of for example, the first bone portion, the second bone portion, and the third bone portion, of the graft unit.

The invention provides a composite bone graft where the one or more pins and the one or more through-holes are configured to provide an interference fit for holding together the graft unit.

The invention also provides a composite bone graft where the one or more through-holes and the one or more pins are round and an inner diameter of a through-hole is smaller than a diameter of a pin, to provide an interference fit between the through-hole and the pin.

The invention further provides a composite bone graft where the one or more cortical bone pins include a plurality of vertical groves provided on a surface thereof.

The invention further provides a composite bone graft where the one or more cortical bone pins includes a roughened surface.

The invention provides a composite bone graft where the one or more cortical bone pins further includes a slot extending from one end of the bone pin.

The invention provides a composite bone graft where the one or more pins is threaded to provide a threaded engagement with the one or more through-holes.

The invention further provides a composite bone graft where the one or more pins is threaded and the one or more through-holes is threaded, to provide a threaded engagement between the one or more pins and the one or more through-holes.

The invention provides a composite bone graft where the one or more pins and the one or more through-holes are configured to provide a slidable connection, for example, to provide a composite bone graft including a substantially void central area.

The invention also provides a composite bone graft where a cross-section of the one or more pins includes a shape selected from the group including the following: round, ovoid, square, rectangular, triangular, pentagon, hexagon, and trapezoidal.

The invention further provides a composite bone graft including a plurality of plate-like cortical bone portions, the cortical bone portions layered to form a graft unit, the graft unit held together with one or more cortical bone pins.

The invention further provides a composite bone graft where the composite bone graft is a cortical cylinder.

The invention provides a composite bone graft including a graft unit having one or more through-holes configured to accomadate one or more pins, the graft unit including two or more bone portions layered to form the graft unit, and one or more pins for holding together the graft unit.

The invention further provides a composite bone graft, including a graft unit having one or more through-holes configured to accomadate one or more pins, the graft unit including a first plate-like cortical bone, a second plate-like cortical bone, a plate-like cancellous bone disposed between the first plate-like cortical bone and the second plate-like cortical bone to form the graft unit, and one or more cortical bone pins for holding together the graft unit.

The invention also provides a composite bone graft, including a graft unit having one or more through-holes configured to accomadate one or more pins, the graft unit including a first plate-like bone, a second plate-like bone provided on the first plate-like bone to form the graft unit, and one or more bone pins for holding together the graft unit.

The invention also provides a cervical composite bone graft, including a flattened curved wedge graft unit having one or more through-holes configured to accomadate one or more pins, the graft unit including two or more plate-like cortical bone portions layered to form the graft unit, and at least two bone pins for holding together the graft unit, where the graft unit includes a substantially centrally located through-hole. The diameter of the through-hole may be readily selected by one of ordinary skill in the art without undue experimentation depending upon the particular application; for example, the diameter of the through-hole may be from about 2.0 mm-4.0 mm; preferably 2.5 mm-3.0 mm; and more preferably 3.0 mm.

The invention also provides a composite bone graft where the one or more through-holes are disposed perpendicular to interfaces of plate-like bones of the graft unit.

The invention provides a composite bone graft where the composite bone graft is a parallelepiped; a parallel block; a square block; a trapezoid wedge; a cylinder; a tapered cylinder; a cervical wedge (flattened curved wedge); an ovoid wedge (anterior lumbar wedge graft) and a polyhedron.

The invention further provides a composite bone graft where the composite bone graft is a polyhedron including six planer surfaces.

The invention provides a composite bone graft where the composite bone graft further includes one or more textured surfaces.

The invention also provides a composite bone graft where the one or more textured surfaces includes a plurality of closely spaced continuous protrusions.

The invention provides a composite bone graft where the continuous protrusions include a cross-section having one or more shapes selected from the following: irregular; triangular, square, rectangular, and curved.

The invention further provides a composite bone graft where the plurality of continuous protrusions are sized to be in a range of greater than or equal to about 1.5 mm in length; 0.5 to about 10.0 mm in width and 0.1 to about 5.0 mm in depth.

The invention provides a composite bone graft where the plurality of closely spaced continuous protrusions are spaced from about 0.0 to about 3.0 mm apart.

The invention provides a composite bone graft where the plurality of protrusions are spaced from about 0.1 to about 2.0 mm apart.

The invention also provides a composite bone graft where the plurality of protrusions are spaced about 0.5 mm apart.

The invention provides a method for restoring vertical support of the posterior and/or anterior column by implanting a composite bone graft including two or more distinct bone portions held together by one or more connectors, at a site in a patient.

The invention provides a composite bone graft containing two or more connected bone portions, where the composite bone graft has a plurality of closely spaced protrusions on one or more surfaces thereof, where the protrusions are continuous protrusions, discrete protrusions, or a combination thereof.

The invention provides a composite bone graft where the plate-like cortical and/or cancellous bone portions are continuous bone portions and/or discontinuous bone portions.

The invention provides a composite bone graft including one or more discontinuous bone portions.

The invention provides a composite bone graft including one or more discontinuous, demineralized cortical bone portions.

The invention provides a composite bone graft including one or more discontinuous, demineralized cancellous bone portions.

The invention further provides a composite bone graft where one or more continuous or discontinuous cancellous bone portions, (continuous or discontinuous and/or demineralized)includes one or more therapeutically beneficial substances including but not limited to, for example, one or more of the following: osteoinductive substances, osteoconductive substances, and pharmaceutically active agents. Such therapeutically beneficial substances may optionally be provided with a carrier. Suitable osteoinductive substances include but are not limited to, for example, autograft bone; allograft bone; Grafton™ produced by Osteotech; DynaGraft™; demineralized cortical bone; demineralized cancellous bone; collagen including one or more growth factors including for example Novus™ produced by Stryker Biotech; collagen including demineralized bone including for example DynaGraft™; cancellous bone; cortical bone; OpteoForm™ produced by the University of Florida; OsteoFill™ produced by the University of Florida; and growth factors including for example bone morphogenic protein, and transforming growth factor-β. Suitable osteoconductive substances include but are not limited to, for example, hydroxyapitate; collagen; any biocompatible matrix material including for example, polymeric matrix materials, bioglass, bioceramics, resorbable

Biomaterials; bioabsorbable polymers; a plastic matrix; stainless steel; titanium; cobalt-chromium-molybdenum alloy matrix; and substances including hydroxyapitate, including for example, Osteoset™ produced by Wright Medical. Suitable pharmaceutically active agents include but are not limited to, for example, growth factors including for example bone growth factors including for example bone morphogenic protein, and transforming growth factor-β; chemotherapeutic agents; anti-inflammatory agents; and antibiotics.

The invention provides a composite bone graft where one or more continuous or discontinuous cancellous bone portions are demineralized and include one or more therapeutically beneficial substances.

The invention provides a composite bone graft where one or more discontinuous cortical bone portions, include one or more therapeutically beneficial substances.

The invention further provides a composite bone graft where one or more discontinuous cortical bone portions are demineralized and include one or more therapeutically beneficial substances.

The invention also provides a composite bone graft including a two or more distinct bone portions held together by one or more connectors, where the composite bone graft includes two diametrically opposing chamfered edges, one provided along the length of the graft at its top edge and the other provided along the length of the graft at its bottom edge, such that the chamfered edges are diametrically opposing.

The invention further provides a composite bone graft including two or more distinct interlocking cortical bone portions.

The invention provides a composite bone graft including two or more distinct interlocking bone portions, where the interlocking bone portions are self-locking.

The invention also provides a composite bone graft including two or more distinct interlocking bone portions, where the interlocking bone portions are locked with one or more locking pins.

The invention further provides a composite bone graft where bone portions are locked with one or more locking pins entirely or partially traversing a dimension of the composite bone graft.

The invention provides an interlocking composite bone graft where each complementary bone portion is provided with a discrete or continuous interlocking pattern.

The invention also provides an interlocking composite bone graft including two or more distinct adjacent bone portions where adjacent bone portions are configured to interlock with each other, and one or more bone pins partially or entirely traversing a dimension of the graft, where the dimension of the graft is the length, width, or height of the graft.

The invention provides an interlocking composite bone graft including two or more distinct adjacent bone portions where adjacent bone portions are configured to interlock with each other.

The invention provides a composite bone graft including two or more distinct adjacent interlocking bone portions where adjacent bone portions include complementary peg-like protrusions and corresponding depressions, such that the protrusions and depressions provide an interlocking fit between the bone portions.

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1. Figure 1 illustrates a perspective view of a trapezoid wedge composite bone graft having a non-textured surface.

Figure 2. Figure 2 illustrates a side view of a trapezoid wedge composite bone graft having opposing textured surfaces provided perpendicular to the interfaces of the bone portions. The textured surfaces illustrate continuous linear protrusions defining a saw-tooth-like pattern.

Figure 3. Figure 3 illustrates a cross-section posterior view of the trapezoid wedge composite bone graft of figure 2.

Figure 4. Figure 4 illustrates a cross-section anterior view of the trapezoid wedge composite bone graft of figure 2.

Figure 5. Figure 5 illustrates a top view of the trapezoid wedge composite bone graft of figure 2, and having a textured surface.

Figure 6. Figure 6 is a perspective view of the trapezoid wedge composite bone graft of figure 2, and having a textured surface.

Figure 7. Figure 7 illustrates a perspective of a preferred slidably connected composite bone graft having a first cortical bone portion, a second cortical bone portion, cortical bone pins, through-holes, and a centrally located void.

Figure 8. Figure 8 illustrates a top view of the slidably connected composite bone graft of figure 7, having a first cortical bone portion, a second cortical bone portion, and a cancellous bone portion disposed there between.

Figure 9. Figure 9 illustrates a perspective view of a preferred embodiment of the composite bone graft.

Figure 10. Figure 10 illustrates a preferred cortical dowel composite bone graft including a plurality of cortical bone portions connected by a single cortical bone pin inserted into a through-hole.

Figure 11A. Figure 11A illustrates the method of making a preferred embodiment of the composite bone graft.

Figure 11B. Figure 11B illustrates a method for producing bone pins and producing a pinned graft unit.

Figure 12. Figure 12 illustrates another method for making a composite bone graft.

Figures 13A & 13B. Figure 13A is a perspective view of a preferred trapezoid block composite bone graft having opposing textured surfaces; Figure 13B is a detail of the protrusions of the textured surface.

Figures 14A, 14B & 14C. Figures 14A, 14B and 14C, illustrate a cervical wedge (flattened curved wedge)composite bone graft for use in cervical fusions where 14A is a perspective standing view, 14B is a side view, and 14C is a perspective view where the graft is provided with opposing textured surfaces.

Figure 15. Figure 15 illustrates a method for making a cervical wedge composite bone graft for use in cervical fusions.

Figure 16. Figure 16 illustrates a perspective view of a mechanical pin connector having a slot extending from its lower end.

Figure 17. Figure 17 illustrates a side view of the mechanical pin connector of figure 16, having a slot extending from its lower end.

Figure 18. Figure 18 illustrates a cross-section view of the mechanical pin connector of figure 16, having a slot extending from its lower end.

Figure 19. Figure 19 illustrates a perspective view of a mechanical pin connector having a plurality of horizontally disposed grooves.

Figure 20. Figure 20 illustrates a perspective view of a mechanical pin connector having helical threads.

Figure 21. Figure 21 illustrates a perspective view of a mechanical pin connector having a plurality of vertically disposed grooves.

Figure 22. Figure 22 illustrates a perspective view of a mechanical slotted pin connector.

Figure 23. Figure 23 illustrates a perspective view of a mechanical pin connector having a plurality of horizontally disposed ridges.

Figure 24. Figure 24 illustrates a perspective view of a mechanical triangular pin connector.

Figure 25. Figure 25 illustrates a perspective view of a mechanical square pin connector

Figure 26. Figure 26 illustrates a perspective view of a mechanical hexagon pin connector.

Figure 27. Figure 27 illustrates a perspective view of a rectangular block composite bone graft having a demineralized cortical bone portion sandwiched between two cortical bone portions, where the demineralized cortical bone portion is provided with perforations and channels, and where the composite graft

includes opposing textured surfaces provided perpendicular to the interfaces of the bone portions. The textured surfaces illustrate continuous linear protrusions defining a saw-tooth-like pattern.

Figure 28. Figure 28 illustrates a perspective view of a rectangular block composite bone graft having a demineralized cancellous bone portion sandwiched between two cortical bone portions, where the composite graft includes opposing textured surfaces provided perpendicular to the interfaces of the bone portions. The textured surfaces illustrate continuous linear protrusions defining a saw-tooth-like pattern.

Figure 29. Figure 29 illustrates a preferred method of making the bone graft of Figure 27.

Figure 30. Figure 30 illustrates a preferred method of making the bone graft of Figure 28.

Figure 31A. Figure 31A illustrates a top view of a composite bone graft including a void disposed between two cortical bone portions where the void includes one or more therapeutically beneficial substances. Figure 31B illustrates a perspective view of a composite bone graft including a void disposed between two cortical bone portions where the void includes one or more therapeutically beneficial substances, and the composite graft includes opposing textured surfaces.

Figure 32A, 32B, & 32C. Figures 32A, 32B, and 32C, illustrate a top view, a cross-section, and a side view, respectively, of a preferred parallel block composite bone graft.

Figure 33A, 33B, & 33C. Figures 33A, 33B, and 33C, illustrate a top view, a cross-section, and a side view, respectively, of a preferred trapezoid wedge composite bone graft.

Figure 34. Figure 34 illustrates a perspective view of a preferred trapezoid wedge composite bone graft having opposing textured surfaces and having a horizontally disposed channel and vertically disposed canals.

Figures 35A & 35B. Figure 35A illustrates a standing view of a preferred cervical wedge composite bone graft for use in cervical fusions, having horizontally disposed channels and having a centrally located through-hole including an osteoconductive substance. Figure 35B illustrates a side view of the cervical wedge graft of Fig. 35A including a vertically disposed channel.

Figures 36A, 36B, & 36C. Figures 36A, 36B, and 36C, illustrate a cross-section, a top view, and a side view, respectively, of a preferred trapezoid wedge composite bone graft.

Figure 37. Figure 37 illustrates a standing view of a cervical wedge (flattened curved wedge)composite bone graft for use in cervical fusions.

Figure 38. Figure 38 illustrates a standing view of a cervical wedge (flattened curved wedge)composite bone graft for use in cervical fusions.

Figures 39. Figure 39 illustrates a perspective view of a preferred embodiment of the composite bone graft including two interlocking cortical bone portions.

Figures 40A & 40B. Figure 40A illustrates a side view of a preferred embodiment of a cervical wedge composite bone graft including two interlocking cortical bone portions, and figure 40B illustrates a perspective view of the graft including two interlocking cortical bone portions.

Figure 41. Figure 41 illustrates a perspective view of a preferred trapezoid wedge bone graft including three interlocking cortical bone portions.

Figures 42A, 42B, & 42C. Figures 42A, 42B, & 42C illustrate side views of preferred composite bone grafts including two interlocking cortical bone portions where the interlocking interface defines a sawtooth pattern, a stepped pattern and a lock & key pattern, respectively.

Figure 43. Figure 43 illustrates a standing view of a cervical wedge (flattened curved wedge)composite bone graft for use in cervical fusions.

Figure 44. Figure 44 illustrates a standing view of a cervical wedge (flattened curved wedge)composite bone graft for use in cervical fusions.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

I. Definitions:

The below definitions serve to provide a clear and consistent understanding of the specification and claims, including the scope to be given such terms.

Bioabsorbable polymers. By the term "bioabsorbable polymers" is intended for the purposes of the present invention, bioresorbable, bioabsorbable, biodegradable, and bioerodible materials that are well known to those of ordinary skill in the art and are described in ***Biomaterials Science-An Introduction to Materials in Medicine***, edited by Ratner, B. D. et al., Academic Press, (1996), and include for example, the following materials: chitosan; isomorphic ploy(hexamethylene co-trans-1,4-cyclohexane dimethylene oxalates); poly(glycolic acid); copolymers of poly(glycolic acid) and poly(lactic acid); polydioxanone; poly(latic acid); polymers having a back-bone structure selected from the group consisting of: polyanhydrides, polyphophazenes, polyphosphonates, polyamides, and polyiminocarbonates; polyhydroxybutyrate; polyhydroxyvalerate; copolymers of polyhydroxybutyrate and polyhydroxyvalerate; polycaprolactone; polydioxanone; poly(γ-ethyl glutamate); poly (DTH iminocarbonate); poly(Bisphenol A iminocarbonate); poly(DETOSU-1,6 HD-t-CDM ortho ester); poly(Sebacic acid-hexadecandioic acid anhydride); poly(ortho esters); poly(amino acids); and PLOA. Such polymers may optionally include one or more pharmaceutically active agents for controlled release applications, such agents including for example: osteoinductive factors including for example bone morphogenic protein; growth factors including for example transforming growth factor-β; chemotherapeutic agents; antiobiotics; and anti-inflammatory agents.

Biocompatible. By the term "biocompatible" is intended for the purposes of the present invention, any material which when implanted in a patient does not provoke an adverse response in the patient. A suitable biocompatible material when introduced into a patient is not toxic or injurious to that patient, or does not cause immunological rejection.

Biomechanical strength. By the term "biomechanical strength" is intended for the purposes of the present invention, those properties exhibited by a bone graft, including loading strength, compressive strength, and tensile strength.

Bone. By the term "bone" is intended for the purposes of the present invention, bone recovered from any source including animal and human, for example, human bone recovered for the production of allografts, and animal bone recovered for the production of xenografts, such allografts and xenografts suitable for implantation into a human. Such bone includes: any bone or portion thereof, including cut pieces of bone, including cortical and/or cancellous bone, for example, recovered from a human including a living human or a cadaver, or animal, and processed for implantation into a living patient. Such bones including for example: the humorous, hemi-pelvi, tibia, fibula, radius, ulna, rib, vertebrae, mandibular, femur, and ilia, and any cut portion thereof. Such bone may be demineralized or not demineralized. In a preferred embodiment a cancellous or cortical bone section is demineralized and disposed between two non-demineralized cortical bone portions. Suitable bone may also include continuous or discontinuous bone portions. For example, one or more bone portions of a composite bone graft may be discontinuous, for example, a bone portion may be perforated and demineralized, for example perforated either before or after demineralization, for example, to allow for uniform demineralization (perforations before demineralization) and to promote ingrowth of patient bone. Cancellous and/or demineralized cancellous and/or discontinuous cancellous and/or demineralized discontinuous cancellous and or discontinuous cortical and/or demineralized discontinuous cortical, bone, may optionally include one or more therapeutically beneficial substances provided with or without a carrier. transforming growth factor-β; The composite bone graft may include a substantially void central area, where the

substantially void central area further includes one or more therapeutically beneficial substances provided with or without a carrier. The material may be in any suitable form including for example, in the form of a solid, sponge, paste and/or gel.

Bone marrow elements. By the term "bone marrow elements" is intended for the purposes of the present invention, the highly cellular hematopoietic connective tissue filling the medullary cavities and spongy epiphysis of bones which may harbor bacterial and/or viral particles and/or fungal particles, and includes for example, blood and lipid.

Chamfer. By the term "chamfer" is intended for the purposes of the invention, an oblique face formed at a corner of a composite bone graft, at an angle to the adjacent principal faces. Suitable angles include angles in the range of from 38° to 52°, more preferably 40° to 50°, even more preferably 42° to 48°, and most preferably about 45°.

Cleaned bone. By the term "cleaned bone" is intended for the purposes of the present invention, a bone or cut portion thereof, that has been processed using means known in the art, to remove bone marrow elements.

Closely Spaced. By the term "closely spaced" is intended for the purposes of the present invention, protrusions (discrete or continuous) which are in close proximity to each other. Preferably the protrusions are spaced no more than 3.0mm apart (i.e. the distance between the edges of two adjacent protrusions), more preferably no more than 2.0mm apart, even more preferably no more than 1.5mm apart, and most preferably about 0.5mm apart

Composite. By the term "composite" is intended for the purposes of the present invention, a bone graft which is made up of two or more distinct bone portions.

Connector. By the term "connector" is intended for the purposes of the present invention, a means of connecting two or more distinct bone portions, including for example a chemical and/or mechanical means. By the term "mechanical connector" is intended for the purposes of the present invention, a structural member including for example, a pin. By the term "chemical connector" is intended for the purposes of the present invention, a biocompatible composition including for example, one or more biocompatible adhesives and one or more surface modification agents and methods.

Continuous Bone Portion. By the term "continuous bone portion" is intended for the purposes of the present invention, a bone portion that is substantially solid without any artificial void areas.

Continuous Protrusion. By the term "continuous protrusion" is intended for the purposes of the present invention, a protrusion whose length continues substantially uninterrupted, including for example a linear or curved protrusion whose length is at least three times greater than its width, preferably at least five times greater, and includes for example a continuous, protruding concentric ring, and a continuous linear protrusion, for example, as illustrated in Fig 2. Each continuous protrusion may or may not be distinct from another continuous protrusion.

Demineralized Bone. By the term "demineralized bone" is intended for the purposes of this invention, one or more distinct bone portions which have been demineralized by any method well known to those of ordinary skill in the art. Cortical bone is preferably demineralized in .5 to .6 N hydrochloric acid for a period of time of from about 1 to about 8 hours, more preferably for a time period of about two hours, at 25°C to 50°C, more preferably at 25°C to 37°C. Cancellous bone is preferably demineralized in .5 to .6N hydrochloric acid for a period of time of from about 20 minutes

to about 6.0 hours, more preferably for a time period of from about 30minutes to about 2.0 hours. Preferably, cortical and/or cancellous bone is demineralized to contain less than 10 wt% residual calcium, more preferably about less than 5 wt% residual calcium, even more preferably about 1 wt% to about 3 wt%, and most preferably about 2 wt% residual calcium. Other methods for demineralizing bone are well known in the art to which the present invention pertains, and can be readily selected and employed by one of ordinary skill in the art, without undue experimentation.

Discontinuous Bone Portion. By the term "discontinuous bone portion" is intended for the purposes of the present invention, a bone portion that contains artificially created void areas including for example, a perforated bone portion, where the perforations or channels may be of any shape and may partially or completely transverse the bone portion. Such perforations may be randomly disposed or disposed in a regular pattern on and/or through the bone portion. Suitable perforations include perforations traversing the width of the bone portion provided perpendicular to the interfaces of the bone portions of the composite graft, and channels traversing the height of the bone portion provided parallel to the interfaces of the bone portions of the composite graft. Such perforations allow for uniform demineralization of a bone portion, and allow for ingrowth of patient bone. A demineralized discontinuous bone portion may be perforated prior to demineralization or after demineralization.

Discrete Protrusion. By the term "discrete protrusion" is intended for the purposes of the present invention, a protrusion which is discontinuous, i.e. which has a distinct length and width, where each discrete protrusion is separate and distinct from every other discrete protrusion, and includes for example a protrusion whose length is less than three times its width, preferably less than twice its width and more preferably a protrusion whose length is about equal to its width.

Interlocking. By the term "interlocking" is intended for the purposes of the present invention, any pattern provided on a bone portion which allows that bone portion to engage or interlace with another bone portion, such that the engaged bone portions act as a single bone portion when stressed. Such bone portions may be provided with engaging patterns including but not limited to the following: step patterns, sawtooth patterns, and ridged patterns, patterns that define mortise and tenon joints, and lock and key type patterns. These patterns may be either discrete, for example one bone portion may include one or more protrusions and a complementary bone portion may be provided with one or more corresponding depressions, or continuous, for example bone portions are provided with complementary continuous grooves (See figs. 39, 40, and 41). The discrete patterns, may include protrusions and corresponding depressions of any shape and size sufficient to provide an interlocking fit, and include round, square, rectangular, triangular, oval, irregular, and any combination of geometric and curved shaped protrusions and corresponding depressions. The depth/height of the discrete or continuous patterns is from about 0.1mm to about 3.5mm, preferably from about 0.2mm to about 2.0mm, more preferably from about 0.3mm to 1.5mm, and most preferably from about 0.5mm to about 1.0mm. One of ordinary skill in the art to which the invention pertain can readily determine, select and employ an appropriate depth/height of the depression/protrusion based on the desired graft dimensions, whether or not a pin will also be used, clinical application, etc., without undue experimentation. Adjacent bone portions provided with interlocking patterns, may be self-locking such that no other connecting means, for example one or more pins, is necessary to form a unitary structure, ie. to hold the composite bone graft together. Alternatively, interlocking bone portions may be "locked" to form a unitary structure using other connection means, for example, one or more pins partially or entirely traversing a

dimension of the composite bone graft, where the dimension is for example the height, width, or length of the composite bone graft.

Load-bearing. By the term "load-bearing" is intended for the purposes of the present invention a non-demineralized bone product for implantation in a patient at a site where the bone graft will be expected to withstand some level of physical load(s).

Locking pin. By the term "locking-pin" is intended for the purposes of the present invention, one or more pins entirely or partially traversing a dimension of a composite bone graft which serve to hold the bone graft together, for example, two or more interlocking bone portions provided with complementary patterns for example, a stepped pattern, may be locked using one or more pins, for example, one bone pin partially traversing the length of the graft.

Mechanical Strength. By the term "mechanical strength" is intended for the purposes of the present invention, the ability of a bone allograft to withstand mechanical loads at an implant site without failing.

Materials properties. By the term "materials properties" is intended for the purposes of the present invention, those properties present in normal fresh bone and include loading strength, compressive strength, tensile strength, and brittleness.

Normal bone. By the term "normal bone" is intended for the purposes of the present invention, fresh hydrated autogenous and/or fresh-frozen hydrated allograft bone tissue.

Osteoconductivity. By the term "osteoconductivity" is intended for the purposes of the present invention, the ability of a substance which by its presence conducts osteoinductive activity. Suitable osteoconductive materials include but are not limited to, for example, one or more biocompatible matrix materials. Suitable osteoconductive substances include but are not limited to,

for example, hydroxyapitate; collagen; any biocompatible matrix material including for example, polymeric matrix materials, bioglass, bioceramics, resorbable Biomaterials, bioabsorbable polymers, a plastic matrix, stainless steel, titanium, and cobalt-chromium-molybdenum alloy matrix; and substances including hydroxyapitate, including for example, Osteoset™ produced by Wright Medical.

Osteoinductivity. By the term "osteoinductivity" is intended for the purposes of the present invention, the ability of a substance to promote bone growth. Suitable osteoinductive substances include but are not limited to, for example, autograft bone; allograft bone; Grafton™ produced by Osteotech; DynaGraft™; demineralized cortical bone; demineralized cancellous bone; collagen including one or more growth factors including for example Novus™ produced by Stryker Biotech; collagen including demineralized bone including for example DynaGraft™; cancellous bone; cortical bone; OpteoForm™ produced by the University of Florida; OsteoFill™ produced by the University of Florida; growth factors including for example, bone morphogenic protein and transforming growth factor-β. Preferably, when a demineralized bone product is used the bone is demineralized to contain less than 6 wt% residual calcium, more preferably demineralized to contain 1 wt% to about 3 wt% residual calcium, and most preferably demineralized to contain about 2 wt% residual calcium.

Parallelepiped. By the term "parallelepiped" is intended for the purposes of the present invention, a six-faced polyhedron all of whose faces are parallelograms lying in pairs of parallel planes.

Polyhedron. By the term "polyhedron" is intended for the purposes of the present invention, a solid formed by plane faces, preferably formed by six faces.

Protrusion. By the term "protrusion" is intended for the purposes of the present invention, an irregularity in a surface of a bone allograft having a height of from 0.1 to 5.00 mm, preferably 0.3 to 3.0 mm, more preferably 0.5 to 1.5 mm, and most preferably .75mm to 1.2mm. The protrusions can be discrete, continuous, or a combination thereof, and can be of any shape including for example: irregular; pyrimidal; conical; cuboidal; rectangular; and cylindrical; or any combination thereof. Further, a cross-section of a continuous or discrete protrusion may be of any shape including for example: irregular; rectangular; square; oval; round; triangular; trapizoidal; and a regular or irregular curve; or any combination thereof. The protrusions can be provided on the bone allograft surface in a regular, symmetric pattern including for example a linear pattern or in an irregular pattern.

Self-locking, interlocking pattern. By the term "self-locking, interlocking pattern" is intended for the purposes of the present invention, any complementary patterns provided on adjacent bone portions which enable the bone portions: to interlock, act as a unitary structure, and the bone portions are held together, without the use of any additional connecting means.

Stability. By the term "stability" is intended for the purposes of the present invention the ability of the present composite bone graft to remain at an implantation site without significantly shifting, rotating, or being extruded.

Stress. By the term "stress" is intended for the purposes of the present invention, load per unit cross-sectional area.

Textured. By the term "textured" is intended for the purposes of the present invention, a composite bone graft having one or more textured surfaces provided on the surface of the composite bone graft where the surface of the composite bone graft can be any surface or a portion of any

surface including a natural surface and/or a cut surface. The textured surface preferably includes a plurality of protrusions provided on the surface or a portion thereof, the protrusions of a shape including for example, irregular; pyrimidal; conical; cuboidal; rectangular; trapizoidal; curved; and cylindrical; or any combination thereof. The protrusions can be discrete, continuous, or a combination thereof.

Therapeutically Beneficial. By the term "therapeutically beneficial" is intended any material which by its action or presence, bring about a therapeutic result in a patient. Such materials include but are not limited to, for example, one or more of the following: osteoinductive substances, osteoconductive substances, and pharmaceutically active agents. Such therapeutically beneficial substances may optionally be provided with a carrier. Suitable osteoinductive substances include but are not limited to, for example, autograft bone; allograft bone; Grafton™ produced by Osteotech; DynaGraft™; demineralized cortical bone; demineralized cancellous bone; collagen including one or more growth factors including for example Novus™ produced by Stryker Biotech; collagen including demineralized bone including for example DynaGraft™; cancellous bone; cortical bone; OpteoForm™ produced by the University of Florida; OsteoFill™ produced by the University of Florida; growth factors including for example bone morphogenic protein, and transforming growth factor-β. Suitable osteoconductive substances include but are not limited to, for example, hydroxyapitate; collagen; any biocompatible matrix material including for example, polymeric matrix materials, bioglass, bioceramics, resorbable Biomaterials; bioabsorbable polymers; a plastic matrix; stainless steel; titanium; cobalt-chromium-molybdenum alloy matrix; and substances including hydroxyapitate, including for example, Osteoset™ produced by Wright Medical. Suitable pharmaceutically active agents include but are not limited to, for example, growth factors including

for example bone growth factors including for example bone morphogenic protein, and transforming growth factor-β, and transforming growth factor-β; chemotherapeutic agents; anti-inflammatory agents; and antibiotics.

II. Procurement and Preliminary Processing of Bone Tissue

Suitable bone tissue includes bone obtained from any animal or human source. Preferably, bone graft tissue can be obtained from the patient himself (autologous bone) or from a cadaver (allograft bone). When allograft bone tissue is used, it is processed under strict aseptic conditions in certified clean room operating suites. The bone tissue is preferably processed to remove all soft tissue, including marrow and blood, to produce a cleaned bone graft. Suitable processing methods are well known to those skilled in the art and can be readily selected and employed by those of ordinary skill in the art without undue experimentation. Suitable methods include the methods disclosed in, for example, United States Patent Nos: 5,556,379; 5,820,581; and 5,797,891.

After processing, the cleaned grafts are packaged under sterile conditions and stored for latter processing into the present composite bone allograft, or immediately processed into the present composite bone allograft followed by appropriate packaging. The use of fresh-frozen and/or freeze-dried, bone allografts are preferred.

III. How to Make a Preferred Embodiment of the Composite Bone Graft.

Figure 11A illustrates a preferred method **60** of making the present composite bone graft. A composite bone graft having of any size necessary for a particular application, can be made using the preferred method discussed hereafter. A cortical bone shaft **61** is obtained from a cadaver and

is transected into cortical sections **62** having a length **63** of at least 18.0 mm, preferably at least 21.0 mm.

A cortical section **62** is then first cut to produce a cortical plank **64**, the remaining cortical section **62a** is turned and again cut to produce a second cortical plank, the remaining cortical plank **62b** is again turned and cut into third and fourth cortical planks **64.** The cortical planks **64** are cut to an appropriate width **65** and thickness **66**. The concave surface **64a** of the plank **64** can be smoothed if needed to produce a smoothed plank **67**. Opposing edges **67a** and **67b** can be cut such that the cut surfaces **67c** and **67d** are approximately parallel. The cut width **68** should be larger than the final composite bone graft width. More specifically, cut width **68** is preferably greater than about 12.0mm.

The convex surface **64b** of plank **64** is then smoothed to produce a smoothed plank **69**. The smoothed plank **64** is further smoothed by for example, milling, such that the opposing surfaces **64a** and **64b**, and **67c** and **67d**, are parallel, to produce a parallel plank **70** having a thickness **71** of at least 1.0 mm, preferably from about 1.5 mm to about 6.0 mm, and more preferably from about 2.0 mm to about 5.5 mm.

Figure 11B illustrates cortical pins **7** cut from a cortical section **62**, using for example a drill press **72** or other means known in the art. The cortical pins **7**, can also be made from a cortical plank **64**, for example by turning on a lathe. The pins **7** have a diameter of from about 1.0 to about 6.0 mm, preferably from about 1.5 mm to about 4.5 mm, and more preferably from about 2.0 mm to about 4.0 mm.

If the composite bone graft includes cancellous bone, cancellous bone planks **73** are produced and sized by the method as described above for producing cortical bone planks **69** and **70**.

The composite bone unit **74** is then assembled as desired, for example a cortical parallel plank **70**, a cancellous plank **73**, and another cortical parallel plank **70**. The composite bone unit **74** has a height **74a**, a width **74b** and a length **74c**. The height **74a**, width **74b** and length **74c**, can be readily selected by one of ordinary skill in the art, depending on factors including for example, the particular application and site of implantation in a patient. The planks are secured and holes **5** are drilled there through. The through-holes **5** are sized such that a tight or frictional fit is provided between a pin **7** and a though-hole **5**. The cortical pins **7** are then inserted through the through-holes **5**, and pressed to fit if needed, to produce pinned composite graft **75**. The cortical bone pins **7** have a diameter **8** sufficient to provide an interference fit or frictional fit between a pin **7** and a through-hole **5**. More specifically the diameter **8** of a cortical pin **7** is generally the same or slightly larger than the diameter **6** of a through-hole **5** into which it is to be inserted. The diameter of the pin **7** is preferably no more than 1.5mm larger than the diameter of the through-hole **5**.

The assembled pinned graft can thereafter be shaped as desired, for example into a trapezoid shaped graft and appropriately dimensioned to produce a composite bone graft. One or more surfaces of the composite bone graft may be textured if desired, for example, depending upon the particular application.

Figure 12 illustrates an additional method **33** of making a preferred embodiment of the present composite bone graft. A cross-section of a femur is obtained from a cadaver, and cleaned using methods well known to those of ordinary skill in the art to which the present invention pertains, to remove bone marrow elements thereby producing the cleaned femural ring **34**. The cleaned femural ring is then sectioned into several sections of cortical bone including a first cortical bone portion **35** and a second cortical bone portion **36**, each portion having a width **37** of from about

2.0 to about 10.0 mm; preferably of from about 4.0 to about 8.0 mm; and more preferably of from about 5.0 to about 6.0 mm. Portions **35** and **36** are then held together to form a graft unit **38** having a width of **39** which is at least 4.0 mm; preferably greater than 9.0 mm; using for example, a clamp, and one or more through-holes **5** having a diameter **6** of about 0.5mm to about 10.0 mm, preferably 2.0mm to about 5.0 mm, more preferably 2.0mm to about 4.0 mm, are then drilled there through.

Cortical pins **7** are produced from cortical bone by methods well known to those of ordinary skill in the art to which the present invention pertains. The pins **7** have a diameter of from 1.0mm to about 6.0 mm, preferably from about 1.5mm to about 4.5mm, and more preferably from about 2.0mm to about 4.0mm. The graft unit **38**, having through-holes **5** drilled there through is then placed in a press and one or more cortical pins **7** are inserted into the through-holes **5**.

Thereafter, one or more surfaces **44** of the composite bone graft **45** can be textured by for example, milling to create a desired texture including the illustrated continuous linear protrusions (sawtooth pattern). Preferably, the composite bone graft includes opposing textured surfaces disposed perpendicular to the interface(s) of the bone portions.

Figure 15 illustrates a preferred method for making a cervical wedge(flattened curved wedge) composite bone graft. Cortical planks **70** are produced and pinned using cortical pins **7** as previously described in Figures 11A and 11B to form a pinned cortical graft unit **89**. The pinned graft unit **89** has a height **90**, a length **91** and a width **92**. The pinned graft unit **89** is then cut and shaped **94** to a designated pattern **93** to form a flattened curved block **95**. A through-hole **83** is then provided centrally through the flattened curved block **95** using for example a drill press **72**. The top **96** and

bottom **97** faces of the block **95** are then provided with a slope at an angle **98** for example by milling. The top **96** and/or bottom **97** faces may optionally be textured, for example by providing the faces with a plurality of pyrimidal protrusions.

Figure 29 illustrates a method of making a composite bone graft **99** including a discontinuous, demineralized, cortical bone portion **100** disposed between two cortical bone portions **70.** The cortical parallel planks **70** are produced as discussed above in reference to Figure 11. The discontinuous, demineralized, cortical bone portion **100** is produced by first producing a cortical parallel plank **70**, as described above in reference to Figure 11. The cortical parallel plank **70** is then perforated, for example using a drill press, to create perforations **101** traversing the width of the plank, and to create channels **102** traversing the height of the plank, to produce a discontinuous bone plank **103**. The discontinuous bone plank **103** is then demineralized by any method well known to those of ordinary skill in the art, including for example, demineralizing in .5-.6N hydrochloric acid at from 25°C to 50°C, preferably at from 25°C to 37°C, for a period of time of from about 1 hour to about 8 hours, preferably for about 2 hours, more preferably demineralization is carried out until the discontinuous bone plank **103** contains less than 6 wt% residual calcium, preferably about 1wt% to about 3wt% residual calcium, and most preferably demineralized to contain about 2 wt% residual calcium, to produce a demineralized discontinuous plank **100**. The demineralized discontinuous bone plank **100** and the cortical parallel planks **70** are then assembled, shaped, and textured to produce the composite bone graft **99**, according to the methods described in reference to Figure 11.

Figure 30 illustrates a method of making a composite bone graft **105** including a demineralized cancellous bone portion **106** disposed between two cortical bone portions **70.** The cortical parallel planks **70** are produced as discussed above in reference to Figure 11. The

demineralized cancellous bone portion **106** is produced by first producing a cancellous parallel plank **73**, as described above in reference to Figure 11. The cancellous parallel plank **73** is then demineralized by any method well known to those of ordinary skill in the art, including for example, demineralizing in .5-.6N hydrochloric acid at from 25°C to 50°C, preferably at from 25°C to 37°C, for a period of time of from about 20 minutes to about 6.0 hours, preferably for about 30 minutes to about 2.0 hour to produce a demineralized cancellous bone plank **106**. More preferably, demineralization is carried out until the bone plank **106** produced, contains less than 6 wt% residual calcium, preferably about 1wt% to about 3wt% residual calcium, and most preferably demineralized to contain about 2 wt% residual calcium. The demineralized cancellous bone plank **106** and the cortical parallel planks **70** are then assembled, shaped, and textured to produce the composite bone graft **105**, according to the methods described in reference to figure 11.

Composite bone grafts including two or more distinct cortical bone portions each bone portion provided with a pattern thereon to enable the bone portions to interlock or engage, are made by first making cortical bone planks as described. After the planks are made they are each provided with a pattern, for example a discrete or continuous pattern. The patterned planks are then fitted together. The patterned planks may be self-locking, ie. provided with a "key" type pattern, to form a unitary structure, or may be locked using one or more pins entirely or partially traversing a dimension, ie. the graft's height, width, and/or length. Thereafter, the locked graft is shaped to form the composite bone graft. Suitable patterns include any complementary patterns which when provided on two or more adjacent bone portions, enable two or more bone portions to act as one, where the patterns are self-locking or are locked with one or more additional connection means, including for example one or more pins.

IV. Description of Preferred Embodiments of the Composite Bone Graft

The present composite bone graft provides a bone graft which can be appropriately sized for any application, has increased stability of the graft at an implant site and promotes the ingrowth of patient bone, while providing excellent mechanical strength.

Figure 1 illustrates a perspective view of a preferred composite bone graft **1** including a first cortical bone portion **2**, a second cortical bone portion **4**, a cancellous bone portion **3** sandwiched between bone portions **2** and **4**, a through-hole **5** having a diameter **6**, and a cortical bone pin **7** having a diameter **8**. The composite bone graft **1**, has a length **9**, a posterior height **13**, an anterior height **11**, a composite width **12**, and section widths **10a**, **10b**, and **10c**.

Figure 2 illustrates a side view of a composite bone graft **1** having opposing textured surfaces **14a** and **14b** provided perpendicular to the interfaces of the bone portions. **14a** and **14b** illustrate continuous linear protrusions defining a saw-tooth-like pattern.

Figure 3 illustrates a cross-section posterior view of composite bone graft **1**, illustrating section widths **10a**, **10b**, and **10c** of bone portions **2**, **3**, and **4**, respectively, and having an anterior height **11** and composite width **12**.

Figure 4 illustrates a cross-section anterior view of composite bone graft **1**, illustrating an posterior height **13** and composite width **12**.

Figure 5 illustrates a top view of composite bone graft **1** illustrating cortical bone portions **2** and **4**, cancellous bone portion **3** disposed there between, and textured surface **14b**.

Figure 6 is a perspective view of composite bone graft **1** illustrating cortical bone portions **2** and **4**, cancellous bone portion **3** disposed there between, textured surfaces **14a** and **14b**, and cortical bone pins **7**.

Figure 7 illustrates a perspective of a preferred composite bone graft **15** having a first cortical bone portion **16**, a second cortical bone portion **17**, cortical bone pins **18**, through-holes **19**, and void **107**, where the diameter of the through-holes **19** and the diameter of the cortical bone pins **18** are configured to allow a slidable connection between the bone portions **16** and **17**, and the bone portions **16** and **17** and the cortical bone pins **18**. The composite bone graft **15** includes a top textured surface **14b** and a bottom textured surface **14a** disposed perpendicular to an interface between bone portions **16** and **17**. Composite bone graft **15** may optionally include one or more cancellous or cortical bone portions disposed between and slidably connected to cortical bone portions **16** and **17**, and to cortical bone pins **18**.

Figure 8 illustrates a top view of composite bone graft **15** having a first cortical bone portion **16**, a second cortical bone portion **17**, and a cancellous bone portion **20** disposed there between, with one portions **16**, **17**, and **20** being slidably connected with cortical bone pins **19**. This graft can be used in place of the traditional iliac crest wedge.

Figure 9 illustrates a perspective view of a preferred composite bone graft **21** including a first cortical bone portion **22**, a second cortical bone portion **23**, a third cortical bone portion **24**, through-holes **5** and cortical bone pins **7**.

Figure 10 illustrates a preferred composite bone graft **25** including a plurality of cortical bone portions including a first cortical bone portion **26**, a second cortical bone portion **27**, a third cortical bone portion **28**, a forth cortical bone portion **29**, a fifth cortical bone portion **30**, and a single cortical bone pin **31** inserted in through-hole **32**. This graft can be used in place of the traditional cloward dowel.

Figure 13A is a perspective view of a preferred trapezoid block composite bone graft having opposing textured surfaces which include a plurality of protrusions **80**, and having a first cortical bone portion **2**, a second cortical bone portion **4**, a cancellous bone portion **3** sandwiched between bone portions **2** and **4**, through-holes **5**, and a cortical bone pins **7** having a diameter **8**. The composite bone graft, has a length **9**, a posterior height **13**, an anterior height **11**, a composite width **12**, section widths **10a**, **10b**, and **10c**, a length **76** which is the length of the graft measured from the anterior end to the center of the first pin **7**, a length **77** which is the length of the graft measured from the center point of a first pin **7** to a center point of a second pin **7**, and a length **78** which is the length of the graft measured from a center point of a second pin to the posterior end of the graft. The textured surface is detailed in Figure 13B. The protrusions **80** have a height of **81**, and are cut in a "saw-tooth" pattern at an angle of **79**.

Figures 14A, 14B and 14C, illustrate a cervical wedge composite bone graft (flattened curved wedge composite bone graft) for use in cervical fusions where 14A is a perspective standing view, 14B is a side view, and 14C is a perspective view where the graft is provided with opposing textured surfaces. The flattened curved wedge composite bone graft includes first and second cortical bone portions **82** held together by two cortical bone pins **7** to form a pinned graft unit, and the pinned graft unit having a hole **83** disposed there through located between pins **7**. The cervical fusion graft has a diameter **84**, a width **85**, an front composite width **87**, and a back composite width **86**. The cervical fusion graft as shown in Figure 14C has textured opposing faces which include a plurality of pyrimidal protrusions **88**.

Figure 16 illustrates a perspective view of a mechanical connector **46** having a slot **47**extending from its lower end.

Figure 17 illustrates a side view of mechanical connector **46** having a slot **47** extending from its lower end.

Figure 18 illustrates a cross-section view of mechanical connector **46** having a slot **47** extending from its lower end.

Figure 19 illustrates a perspective view of a mechanical connector **48** having a plurality of horizontally disposed grooves **49**.

Figure 20 illustrates a perspective view of a mechanical connector **50** having helical threads **51**.

Figure 21 illustrates a perspective view of a mechanical connector **52** having a plurality of vertically disposed grooves **53**.

Figure 22 illustrates a perspective view of a mechanical slotted pin connector **54**.

Figure 23 illustrates a perspective view of a mechanical connector **55** having a plurality of horizontally disposed ridges **56**.

Figure 24 illustrates a perspective view of a mechanical triangular pin connector **57**.

Figure 25 illustrates a perspective view of a mechanical square pin connector **58**.

Figure 26 illustrates a perspective view of a mechanical hexagon pin connector **59**.

Figure 27 illustrates a perspective view of a rectangular block composite bone graft **99**, including a first cortical bone portion **2**, a second cortical bone portion **4**, a discontinuous, demineralized cortical bone portion **104** disposed between cortical bone portions **2** and **4**, where the discontinuous, demineralized cortical bone portion **100** includes perforations traversing the width of the bone portion **100** and are disposed perpendicular to the interfaces of the bone portions **2**, **100** and **4**, and channels **102** traversing the height of bone portion **100** and are disposed parallel to the

interfaces of the bone portions **2**, **100**, and **4**, through-holes **5**, and cortical bone pins **7**. The composite bone graft **99** includes opposing textured surfaces **14a** and **14b** provided perpendicular to the interfaces of the bone portions and defining a saw-tooth-like pattern.

Figure 28 illustrates a perspective view of a rectangular block composite bone graft **105**, including a first cortical bone portion **2**, a second cortical bone portion **4**, a demineralized cancellous bone portion **106** disposed between cortical bone portions **2** and **4**, through-holes **5**, and cortical bone pins **7**. The composite bone graft **105** includes opposing textured surfaces **14a** and **14b** provided perpendicular to the interfaces of the bone portions and defining a saw-tooth-like pattern.

Figure 31A illustrates a top view of a rectangular block composite bone graft **108**, including a first cortical bone portion **2**, a second cortical bone portion **4**, a void **107** disposed between cortical bone portions **2** and **4**, and cortical bone pins **7**. The void **107** includes one or more therapeutically beneficial substances **109**.

Figure 31B illustrates a perspective view of a rectangular block composite bone graft **108**, including a first cortical bone portion **2**, a second cortical bone portion **4**, a void **107** disposed between cortical bone portions **2** and **4**, through-holes **5**, and cortical bone pins **7**. The void **107** includes one or more therapeutically beneficial substances **109**. The composite bone graft **108** includes opposing textured surfaces **14a** and **14b** provided perpendicular to the interfaces of the bone portions **2** and **4**, with the therapeutically beneficial substance **109**, and defining a saw-tooth-like pattern.

Figures 32A, 32B and 32C, illustrate a parallel block composite bone graft where 32A is a cross-section view, 32B is a top-view, and 32C is a is a side view of the width of the composite graft., where the graft is provided with opposing textured surfaces. The composite bone graft

includes first and second cortical bone units **110**, a cancellous bone portion **3** sandwiched between bone units **110**, through-holes **5**, and a cortical bone pins **7** (The diameter of each bone pin may be the same or different depending on the particular application, implant and size of the graft, the diameter of a pin is preferably about 1.0 to about 5.0 mm, more preferably from about 1.5 mm to about 4.0 mm, even more preferably from about 2.0 to about 3.5 mm, and most preferably 2.5 to 3.0 mm). The composite bone graft, has a length **9** (preferably from 5.0 to about 50.0 mm, more preferably from about 10.0 to about 30.0 mm, even more preferably from about 15.0 mm to about 25.0 mm, and most preferably about 21.0 mm), a height **112** (preferably from about 3.0 mm to about 30.0 mm, more preferably from about 5.0 mm to about 25.0mm, even more preferably from about 8.0 mm to about 15.0 mm), a composite width **12** (preferably from about 4.0 mm to about 20.0 mm, more preferably from about 5.0 mm to about 15.0 mm), section widths **10a**, **10b**, and **10c,** which are preferably 4.0 mm, 3.0 mm, and 4.0 mm; 4.0 mm, 5.0 mm, and 4.0 mm; and 3.0 mm, 5.0 mm, and 3.0 mm; respectively, where two bone portions **111** are layered to form the bone unit **110**, and where the width of each bone portion **111** is such that when layered with another bone portion **111**, the resultant width **113** is as desired, for example, 4.0mm. The bone graft has a length **76** (for example when the length of the graft is 21.0 mm, length 76 is preferably about 7.5 mm) which is the length of the graft measured from the anterior end to the center of the first pin **7**, a length **77** (for example when the length of the graft is 21.0 mm, length 77 is preferably about 8.0 mm) which is the length of the graft measured from the center point of a first pin **7** to a center point of a second pin **7**, and a length **78** (for example when the length of the graft is 21.0 mm, length 78 is preferably about 5.5 mm) which is the length of the graft measured from a center point of a second pin to the posterior end of the graft. The protrusions **80** have a height of **81** (preferably from about 0.5 mm to about 2.5

mm, more preferably from about 1.0 mm to about 2.0 mm, and most preferably from about 1.1 mm to about 1.6 mm), and are cut in a "saw-tooth" pattern at an angle (preferably about 60°).

Figures 33A, 33B, and 33C, illustrate a trapezoid wedge composite where 33A is a cross-section view, 33B is a top-view, and 33C is a side view of the width of the composite graft. The composite bone graft includes first and second cortical bone units **110**, a cancellous bone portion **3** sandwiched between bone units **110**, through-holes **5**, and a cortical bone pins **7** (The diameter of each bone pin may be the same or different depending on the particular application, implant and size of the graft, the diameter of a pin is preferably about 1.0 to about 5.0 mm, more preferably from about 1.5 to about 4.0 mm, even more preferably from about 2.0 to about 3.5 mm, and most preferably 2.5 to 3.0 mm). The composite bone graft, has a length **9** (preferably from 5.0 to about 50.0 mm, more preferably from about 10.0 to about 30.0 mm, even more preferably from about 15.0 mm to about 25.0 mm, and most preferably about 21.0mm), an anterior height **11** (preferably from about 3.0 mm to about 30.0 mm, more preferably from about 5.0 mm to about 25.0mm, even more preferably from about 8.0 mm to about 15.0 mm), a posterior height **13** (preferably from about 5.0 mm to about 50.0 mm, more preferably from about 7.0 mm to about 25.0 mm, and even more preferably from about 10.0 to about 15.0 mm), a composite width **12** (preferably from about 4.0 mm to about 20.0 mm, more preferably from about 5.0 mm to about 15.0 mm, section widths **10a**, **10b**, and **10c**, which are preferably 4.0 mm, 3.0 mm, and 4.0mm; 4.0 mm, 5.0 mm, and 4.0 mm; and 3.0 mm, 5.0 mm, and 3.0 mm; respectively, where two bone portions **111** are layered to form the bone unit **110**, and where the width of each bone portion **111** is such that when layered with another bone portion **111**, the resultant width **10a** or **10c** is as desired, for example, 4.0mm. The bone graft has a length **76** (for example when the length of the graft is 21.0 mm, length 76 is preferably about 7.5

mm) which is the length of the graft measured from the anterior end to the center of the first pin **7**, a length **77** (for example when the length of the graft is 21.0 mm, length 77 is preferably about 8.0 mm) which is the length of the graft measured from the center point of a first pin **7** to a center point of a second pin **7**, and a length **78** (for example when the length of the graft is 21.0 mm, length 78 is preferably about 5.5 mm) which is the length of the graft measured from a center point of a second pin to the posterior end of the graft.. The protrusions **80** have a height of **81** (preferably from about 0.5 mm to about 2.5 mm, more preferably from about 1.0 mm to about 2.0 mm, and most preferably from about 1.1 mm to about 1.6 mm), and are cut in a "saw-tooth" pattern at an angle (preferably about 60°).

Figure 34 illustrates a trapezoid wedge composite bone graft **113** including a first cortical bone portion **2**, a second cortical bone portion **4**, opposing textured surfaces **14a** and **14b**, vertically disposed channels **114** (preferably channels 114 have a diameter of from 0.25 mm to about 5.0 mm, more preferably from about) 0.5 mm to about 4.0 mm, and most preferably from about 1.0 mm to about 3.0 mm), and horizontally disposed channel **115** (preferably channels 115 have a diameter of from about 0.5 to about 6.0 mm, more preferably from about 1.0 mm to about 5.0 mm, and most preferably from about 2.0 mm to about 4.0 mm). The composite bone graft also includes cortical bone pins **7** (preferably bone pins 7 have a diameter of from about 2.0 mm to about 3.5 mm, more preferably from about 2.5 mm to about 3.0 mm, where each pin may have the same or a different diameter) and through-holes **5**. The channels may optionally include one or more therapeutically beneficial substances. The graft has a length **9** (preferably from 5.0 to about 50.0 mm, more preferably from about 10.0 to about 30.0 mm, even more preferably from about 15.0 mm to about 25.0 mm, and most preferably about 21.0mm), an front height **11** (preferably from about 3.0 mm to

about 30.0 mm, more preferably from about 5.0 mm to about 25.0mm, even more preferably from about 8.0 mm to about 15.0 mm), a back height **13** (preferably from about 5.0 mm to about 50.0 mm, more preferably from about 7.0 mm to about 25.0 mm, and even more preferably from about 10.0 to about 15.0 mm), a composite width **12** (preferably from about 4.0 mm to about 20.0 mm, more preferably from about 5.0 mm to about 15.0 mm and most preferably about 6.0 mm to about 8.0 mm), and a section width **116** (preferably from about 1.0 mm to about 5.0 mm, more preferably from about 2.0 mm to about 4.0 mm, and most preferably from about 3.0 mm to about 3.5 mm).

Figure 35A illustrates a standing view of a cervical wedge composite bone graft having a textured surface **117a**. The cervical wedge composite bone graft includes first and second cortical bone portions **82** held together by two cortical bone pins **7** to form a pinned graft unit, and the pinned graft unit having a through-hole **83** (preferably from about 2.0 mm to about 8.0 mm in diameter, more preferably from about 3.0 mm to about 5.0 mm) disposed there through located between pins 7. The cervical fusion graft has a diameter **84**, a width **85**, a front composite width **87**, and a back composite width **86**. The cervical wedge also includes horizontally disposed channels **115** (preferably channels 115 have a diameter of from about 0.5 to about 10.0 mm, more preferably from about 1.0 mm to about 5.0 mm, and most preferably from about 2.0 mm to about 4.0 mm), and one or more therapeutically beneficial substances **109**, for example cancellous bone or demineralized cancellous bone, disposed in through-hole **83** and/or channels **115**. Figure 35B illustrates a side view of the cervical wedge composite bone graft of Fig. 35A and includes opposing textured surfaces **117a** and **117b**, and a vertically disposed channel **118**. The top and bottom surfaces of the graft are sloped at angel **119** and **120**, respectively. Angle **119** is preferably from about 0° to about 10°, more preferably from about 0° to about 7°, and in this figure it is 0°. Angle **120** is preferably from about

0° to about 10°, more preferably from about 0° to about 7°, and in this figure the angle is 7°, that is the graft slopes at 7°.

Figures 36A, 36B, and 36C, illustrate a trapezoid wedge composite bone graft including two cortical bone portions where 36A is a cross-section view, 36B is a top-view, and 36C is a side view of the width of the composite graft. The composite bone graft includes first and second cortical bone portions **2** and **4**, , through-holes **5**, and a cortical bone pins **7** (The diameter of each bone pin may be the same or different depending on the particular application, implant and size of the graft, the diameter of a pin is preferably about 1.0 to about 5.0 mm, more preferably from about 1.5 to about 4.0 mm, even more preferably from about 2.0 to about 3.5 mm, and most preferably 2.5 to 3.0 mm). The composite bone graft, has a length **9** (preferably from 5.0 to about 50.0 mm, more preferably from about 10.0 to about 30.0 mm, even more preferably from about 15.0 mm to about 25.0 mm, and most preferably about 21.0mm to 23mm), an anterior (shorter) height **11** (preferably from about 3.0 mm to about 30.0 mm, more preferably from about 5.0 mm to about 25.0mm, even more preferably from about 8.0 mm to about 15.0 mm), a posterior (longer) height **13** (preferably from about 5.0 mm to about 50.0 mm, more preferably from about 7.0 mm to about 25.0 mm, and even more preferably from about 10.0 to about 15.0 mm), a composite width **12** (preferably from about 4.0 mm to about 20.0 mm, more preferably from about 5.0 mm to about 15.0 mm, section widths **124,** which are preferably from about 2.0mm to about 5.0mm, more preferably from about 2.5mm to about 4.0mm, and most preferably about 3.5mm $\pm$ 0.5mm. The bone graft has a length **122** (for example when the length of the graft is 23.0 mm, length 122 is preferably about 5.5mm) which is the length of the graft measured from the posterior (longer) end to the center of the first pin **7**, a length **123** (for example when the length of the graft is 23.0 mm, length 123 is preferably about 13.5

mm) which is the length of the graft measured from the posterior (longer) end to the center point of the second pin **7**. The graft is chamfered at diametrically opposed edges including edge **140** at an angle **125** of preferably about 45° at a depth **126** of preferably about 0.5mm. The wedge graft has a slope **121** of preferably from about 3.0° to about 13.0°, more preferably from about 5.0° to about 11.0°, and most preferably about 5.4° or 10.8° depending on the anterior and posterior heights.

Figure 37 illustrates a cross-section view of a cervical wedge composite bone graft (flattened curved wedge composite bone graft) for use in cervical fusions. The flattened curved wedge composite bone graft includes two or more cortical bone portions held together by two cortical bone pins **7** to form a pinned graft unit, and the pinned graft unit having a hole **83** disposed there through located between pins **7** and having a diameter **130** of from about 3.0mm to about 7.0mm, more preferably from about 4.0mm to about 6.0mm, and most preferably about 4.0mm to 5.0mm. The distance **127** between hole **83** and second width **129**, and between pins **7** and arc **137**, is preferably 1.0mm to 3.5mm, more preferably about 1.5mm to about 3.0mm and even more preferably about 2.0mm. The distance**128** between hole **83** and pins **7** is preferably from1.5mm to 3.5mm, more preferably from 2.0mm to about 3.0mm, and most preferably is about 2.25mm to 2.75mm. The cervical fusion graft has a diameter **84** of from about 10.0mm to about 20.0mm, more preferably from about 12.0mm to about 16.0mm, and most preferably about 12.0mm to14.0mm, a width **85** of from about 14.0mm to about 24.0mm, more preferably from about 15.0mm to about 20.0mm, and most preferably about 15.5mm to17.5mm, and a second width **129** of from about 8.0mm to about 16.0mm, more preferably from about 10.0mm to about 14.0mm, and most preferably about 11.0mm to12.0mm. Slope **136** is preferably about 15° to about 30°, more preferably about 20° to about 25°, and most preferably about 20°.

Figure 38 illustrates a cross-section view of a cervical wedge composite bone graft (flattened curved wedge composite bone graft) for use in cervical fusions. The flattened curved wedge composite bone graft includes two or more cortical bone portions held together by two cortical bone pins **7** to form a pinned graft unit, and the pinned graft unit having a hole **83** disposed there through located between pins **7** and hole **83** having a height **131** of from about 5.0mm to about 15.0mm, more preferably from about 6.0mm to about 12.0mm, and most preferably about 8.0mm to 10.0mm, and having a width **130** of from 3.0mm to about 7.0mm, more preferably from about 4.0mm to about 6.0mm, and most preferably about 4.0mm to 5.0mm. The distance **127** between hole **83** and second width **129**, and between pins **7** and arc **137**, is preferably 1.0mm to 3.5mm, more preferably about 1.5mm to about 3.0mm and even more preferably about 2.0mm. The distance**128** between hole **83** and pins **7** is preferably from1.5mm to 3.5mm, more preferably from 1.0mm to about 3.0mm, and most preferably is about 2.0mm. The cervical fusion graft has a diameter **84** of from about 10.0mm to about 20.0mm, more preferably from about 12.0mm to about 16.0mm, and most preferably about 12.0mm to14.0mm, a width **85** of from about 14.0mm to about 24.0mm, more preferably from about 15.0mm to about 20.0mm, and most preferably about 15.5mm to17.5mm, and a second width **129** of from about 8.0mm to about 16.0mm, more preferably from about 10.0mm to about 14.0mm, and most preferably about 11.0mm to12.0mm. Slope **136** is preferably about 15° to about 30°, more preferably about 20° to about 25°, and most preferably about 20°.

Figure 39 illustrates a perspective view of a preferred composite bone graft including cortical bone portions **132**, and a cortical bone pins **7**. The cortical bone portions **132** are patterned with grooves **133** running in direction **135** to provide an interlocking fit between the bone portions **132**.

Figures 40A and 40B illustrate a wedge composite bone graft (flattened curved wedge composite bone graft) for use in cervical fusions where 14A is a standing side view, and 14B is a perspective view. The flattened curved wedge composite bone graft includes first and second cortical bone portions **132** held together by two cortical bone pins **7** to form a pinned graft unit, and the pinned graft unit having a hole **83** disposed there through located between pins **7**. The cortical bone portions **132** are patterned with grooves **133** running in direction **135** to provide an interlocking fit between the bone portions **132**.

Figure 41 illustrates a perspective view of a preferred composite bone graft including cortical bone portions **132** and **134**, and a cortical bone pins **7**. The cortical bone portions **132** and **134** are patterned with grooves **133** running in direction **135** to provide an interlocking fit between the bone portions **132**.

Figures 42A, 42B, and 42C illustrate side views of a preferred composite bone graft including two patterned cortical bone portions **132** having a pattern **133**, **138**, and **139**, respectively, where the bone portions are interlocked with each other. Figure 42C illustrates a self-locking, interlocking pattern **139**.

Figure 43 illustrates a cross-section view of a cervical wedge composite bone graft (flattened curved wedge composite bone graft) for use in cervical fusions. The flattened curved wedge composite bone graft includes two or more cortical bone portions held together by two cortical bone pins **7** having a diameter of from 1.0mm to about 4.0mm, preferably from about 2.0mm to about 3.0mm and more preferably about 2.5mm, to form a pinned graft unit, and the pinned graft unit having a hole **83** disposed there through located between pins **7**, and hole **83** having a width **130** of from 3.0mm to about 7.0mm, more preferably from about 4.0mm to about 6.0mm, and most

preferably about 4.0mm to 5.0mm. The distance **127** between hole **83** and second width **129**, and between pins **7** and arc **137**, is preferably 1.0mm to 3.5mm, more preferably about 1.5mm to about 3.0mm and even more preferably about 2.0mm. The distance**128** between hole **83** and pins **7** is preferably from1.5mm to 3.5mm, more preferably from 1.0mm to about 3.0mm, and most preferably is about 2.0mm. The cervical fusion graft has a diameter **84** of from about 10.0mm to about 20.0mm, more preferably from about 12.0mm to about 16.0mm, and most preferably about 11.0mm to13.0mm, a width **85** of from about 10.0mm to about 24.0mm, more preferably from about 12.0mm to about 20.0mm, and most preferably about 13.5mm to15.5mm, and a second width **129** of from about 4.0mm to about 12.0mm, more preferably from about 6.0mm to about 10.0mm, and most preferably about 7.0mm to about 8.0mm. Slope **136** is preferably about 25°.

Figure 44 illustrates a cross-section view of a cervical wedge composite bone graft (flattened curved wedge composite bone graft) for use in cervical fusions. The flattened curved wedge composite bone graft includes two or more cortical bone portions held together by two cortical bone pins **7** having a diameter of from 1.0mm to about 4.0mm, preferably from about 2.0mm to about 3.0mm and more preferably about 2.5mm, to form a pinned graft unit, and the pinned graft unit having a hole **83** disposed there through located between pins **7**, and hole **83** having a diameter **130** of from 3.0mm to about 9.0mm, more preferably from about 4.0mm to about 8.0mm, and most preferably about 6.0mm to 7.0mm, and a width **141** of from about 5.0mm to about 13.0mm, preferably from about 7.0mm to about 11.0mm, more preferably from about 8.5mm to about 9.5mm, and most preferably about 9.0mm. Hole **83** has a second width **140** of from about 2.0mm to about 6.0mm, preferably from about 3.0mm to about 5.0mm, and more preferably form about 3.5mm to about 4.5mm. The distance **127** between hole **83** and second width **129**, and between pins 7 and arc

137, is preferably 1.0mm to 3.5mm, more preferably about 1.5mm to about 3.0mm and even more preferably about 2.0mm. The cervical fusion graft has a diameter **84** of from about 10.0mm to about 20.0mm, more preferably from about 12.0mm to about 16.0mm, and most preferably about 13.0mm to15.0mm, a width **85** of from about 10.0mm to about 24.0mm, more preferably from about 12.0mm to about 20.0mm, and most preferably about 16.5mm to18.5mm, and a second width **129** of from about 6.0mm to about 14.0mm, more preferably from about 8.0mm to about 12.0mm, and most preferably about 9.0mm to11.0mm. Slope **136** is preferably about 25°.

The present composite bone graft can include two or more bone portions, including any combination of cancellous and cortical bone portions, or cancellous or cortical bone portions alone, where the bone portions may optionally be demineralized, and may optionally be discontinuous, where the bone portions are connected, for example by interlocking the bone portions, and/or by one or more mechanical and/or chemical connectors. Any cancellous bone portion and/or discontinuous bone portion (cortical and/or cancellous), and/or any demineralized bone portion (cortical and/or cancellous) may optionally include one or more pharmaceutically active agents or therapeutically beneficial substances provided therein, for example provided in the matrix of cancellous bone, or provided in any artificially created void areas. Both the cortical and cancellous bone portions may be solid and continuous or may be discontinuous (i.e. include one or more "holes" or "perforations" of any shape disposed at regular or random intervals throughout the bone portion. Bone portions may be provided with a pattern to enable an interlocking fit between cortical bone portions.

Suitable mechanical connectors include pin-type structures having any cross-section shape, such shapes including for example, round, square, triangular, rectangular, hexagon, pentagon, oval, and irregular. The pin-type structure can include surface modification, for example the surface can

be roughened, or provided with a plurality of horizontally or vertically disposed grooves (horizontal or vertically relative to the length of the pin); horizontally or vertically disposed ridges; or helical threads. The pin or surface-modified pin can also include one or more slots extending partially or entirely through the diameter of the pin, and extending partially or entirely through the length of the pin, suitable slots include for example, a slot extending partially through the diameter of the pin, for example about half-way through the diameter of the pin, and through the entire length of the pin; and a slot extending entirely through the diameter of the pin, and extending through a partial length of the pin for example, extending at least half-way through the length of the pin, preferably extending no more than about seven-eighths the length of the pin. Suitable mechanical connectors also include cotter pins. A composite graft can be pinned with one or more biocompatible pins, where the pins have substantially the same diameter or have a diameter different from each other. Suitable diameters can be readily selected and employed by one of ordinary skill in the art to which the present invention pertains without undue experimentation depending upon, for example, the particular application and implantation site, and the size and shape of the composite graft. The composite graft can be pinned with one or more biocompatible pins, entirely or partially traversing a dimension of the graft, for example, the height, length, and/or width of the composite graft. One of ordinary skill in the art to which the present invention pertains can readily select an appropriate pin, number of pins, and determine the orientation of the pin or pins, based on for example, the particular graft, whether the graft is interlocking or not, the orientation of the graft in the body, and the clinical indication, without undue experimentation.

Suitable chemical connectors include any biocompatible adhesive. Such adhesives are well known to those of ordinary skill in the art to which the present invention pertains, and can be readily

selected and employed by those of ordinary skill in the art, without undue experimentation. Suitable chemical connectors also include known methods of biochemical surface modification. Such methods are well known to those of ordinary skill in the art to which the present invention pertains, and can be readily selected and employed by those of ordinary skill in the art, without undue experimentation.

The chemical and/or mechanical connectors may be used alone or in any combination and may include one or more therapeutically beneficial substances including for example, one or more osteoinductive substances, one or more osteoconductive substances and one or more pharmaceutically active agents.

The through-hole(s) of the composite bone graft may also include surface modification as described above for the present mechanical connectors configured to accomadate a particular mechanical connector. For example, if a threaded cortical bone pin is used, the through-hole or holes can optionally be threaded. The through-hole(s) can traverse any dimension of the graft, provided that they are placed such that when graft unit is connected the graft is held together. One of ordinary skill in the art to which the present invention pertains can readily select an optimum location for the through-holes based on criteria including the following: the anterior and posterior height of the composite bone graft, and the diameter of the mechanical and/or mechanical and chemical connectors, and the height of the protrusions. For example, when the anterior height is relatively small (i.e. 7.0mm) and the diameter of the pin is relatively large (i.e.2.5-3.0mm), the through-holes can be spaced equidistant along the length of the graft unit, or displaced toward the posterior end of the graft unit.

The graft unit can be connected with one or more mechanical connectors. Suitable connection include any connection which is adequate to hold the bone portions of the graft unit together. Such connections include, for example, an interference or friction connection where the diameter of the pin is the same as or slightly larger than (preferably no more than 1.5 mm larger than the diameter of the through-hole) the diameter of the corresponding through-hole; a slidable connection where the diameter of the pin is the slightly less than the diameter of the through-hole, and a compression fit, where the pin is configured to allow compression upon insertion where the pin expands after insertion, achieved for example, by providing the pin with a slot.

The mechanical connector of the invention, including pin-like connectors can be composed of any biocompatible material sufficient to hold together the present graft unit. Suitable biocompatible materials include for example, cortical bone; stainless steel; titanium; cobalt-chromium-molybdenum alloy; and a plastic for example, of one or more of the following: nylon, polycarbonate, polypropylene, polyacetal, polyethylene, and polysulfone, where the plastic can optionally include fibers; and a polymer including one or more bioabsorbable polymers including resorbable calcium phosphates; bioceramics and/or glasses including for example bioactive glasses and glass-ceramics; and calcium phosphate ceramics. Such mechanical connectors including for example, bioabsorbable polymers may optionally include one or more active agents, including for example one or more pharmaceutically active agents and/or one or more therapeutically beneficial agents, provided on the surface or impregnated in the matrix of the material.

The surface of the mechanical connector can be modified by methods well known to those of ordinary skill in the art to which the invention pertains, and include for example the following: (a) modification to influence cell adhesion and growth, provided by: (I) oxidized polystyrene surface,

(ii) ammonia plasma-treated surface, and (iii) plasma-deposited acetone or methanol film; (b) modification to control protein adsorption; and (c) modification to improve lubricity.

The composite bone graft preferably has a shape including for example, a square, rectangular or curved block; a flattened curved wedge (ie. a cervical wedge for use in cervical fusion); a wedge; a trapezoid wedge; a polyhedron block, a parallelepiped; a cylinder or dowel having a uniform diameter or a decreasing or increasing diameter, for example a tapered cylinder or tapered dowel; a dowel or tapered dowel having a cross-section of a shape including for example, round, oval, square, rectangular, triangular, pentagon, or hexagon.

The composite bone graft can include one or more partially or completely textured surfaces. Preferably, a textured composite bone graft includes opposing textured surfaces disposed perpendicular to the interface(s) of the bone portions. The textured surface of the composite bone graft includes a plurality of protrusions. The protrusions can be formed over an entire surface of the composite bone graft or over a portion of a surface, for example over the entire cut surfaces, or over a portion of the cut surfaces. The plurality of protrusions can be formed on the surface in any number of ways well known to those of ordinary skill in the art to which the present invention pertains, including for example mechanical and/or chemical methods, including for example, by forming a series of parallel linear or curved grooves. The bone allograft protrusions can be formed by milling, for example by milling a set of parallel linear groves to form a saw-tooth configuration on the cut surface of the composite graft to form continuous linear protrusions; by milling a first set of parallel linear groves followed by turning the graft and forming a second set of parallel grooves at an angle to the first series, for example, at a 90° angle to form a plurality of discrete pyrimidal protrusions. Milling is preferably achieved , by for example: running the graft over a milling tool

which includes a plurality of closely spaced blades which can be adjusted to achieve a desired height and width; to form the discrete pyrimidal protrusions, the graft can then be turned at, for example, a 90° angle and again run over the milling tool to produce the discrete protrusions illustrated. Milling can also be achieved using for example a routing or dremel tool, a laser, and masking and acid etching.

Other protrusions, for example concentric rings or other curved or irregular, or regular protrusions can be provided by attaching a drill bit having a blade corresponding to the protrusion pattern desired where the blade is appropriately sized to provide a desired protrusion width, length, and height, to a drill and drilling the desired surface of the bone to achieve the desired textured surface. One of ordinary skill in the art can readily design and produce, or select, and employ an appropriate milling tool to achieve a desired textured surface on a bone allograft, without undue experimentation.

Preferably, the protrusions (discrete, continuous, or a combination thereof) present on one or more surfaces of the present allograft are closely spaced, preferably from about 0.0 to 3.0 mm apart, preferably 0.1 to 2.0 mm apart, more preferably about 0.2 to 1.5 mm apart, and most preferably about 0.5 mm apart, (that is, there is preferably a distance of from 0.0 to 3.0 mm between the edges of two adjacent protrusions). The protrusions preferably have a height of from 0.1 to 5.00 mm, preferably 0.3 to 3.0 mm, more preferably 0.5 to 1.5 mm, and even more preferably .75 mm to 1.3mm, and most preferably about 1.2 mm.

The composite bone graft may include one or more void areas. Examples of such grafts include a composite graft having for example a first and a second cortical bone portion where the bone portions are for example slidably connected with for example one or more bone pins, where

the first and second bone portion are disposed apart thereby creating a centrally located void. The void may optionally include any pharmaceutically active agent and/or therapeutically beneficial agent, including for example, osteoinductive substances including for example, bone morphogenic protein, hydroxyapitate, demineralized bone and bone products including for example GRAFTON and DYNEGRAFT, and autograft bone; such substances may be in any form including for example, in the form of a paste, gel, or sponge.

IV. Use of the Composite Bone grafts

The present composite bone grafts are useful in spinal applications including restoration of column support and are preferably used from the posterior approach. Composite grafts suitable for posterior lumbar interbody fusions include for example the following described in detail below: **(a)** composite bone grafts having a trapezoid wedge shape and optionally having opposing textured surfaces disposed perpendicular to the interfaces of the bone portions, **(b)** composite bone grafts having a parallel block shape and optionally having opposing textured surfaces disposed perpendicular to the interfaces of the bone portions, **(c)** composite bone grafts having a large square block shape and optionally having opposing textured surfaces disposed perpendicular to the interfaces of the bone portions,**(d)** composite bone graft blocks having a flattened curved wedge shape and optionally having opposing textured surfaces disposed perpendicular to the interfaces of the bone portions for use in for example, cervical fusion, (which can be used from an anterior or posterior approach) and **(e)** composite bone grafts having an ovoid wedge shape for performing anterior fusions (which can be used from an anterior or posterior approach).

The term "about" used below and throughout this disclosure in reference to specific dimensions means that the tolerance limits for overall or outer dimensions of the composite bone graft is plus or minus (+/-) 1.0 mm, and the tolerance limits for the width of individual cortical bone portions is plus or minus (+/-) 0.5 mm.

The composite bone grafts having a trapezoid wedge shape, the shape as shown in Figure 1, and optionally having opposing textured surfaces disposed perpendicular to the interfaces of the bone portions, preferably include two or more bone portions where the bone portions can be cortical or cancellous bone portions or a combination thereof, each bone portion having a width of from about 1.5 mm to about 10.0 mm, preferably from about 2.0 mm to about 7.0 mm, more preferably from about 2.0 mm to about 5.0 mm, and most preferably having a width of about2.0mm to about 4.0 mm, to give a composite width of from about 8.0 mm to about 15.0mm, preferably from about 9.0mm to about 13.00mm, and more preferably about 11.0mm.

The trapezoid wedge composite bone graft has a front (anterior) height which is smaller than its back (posterior) height, the anterior height being from about 5.0 mm to about 15.0 mm, preferably from about 6.0 mm to about 13.0 mm, more preferably from about 7.0 mm to about 12.0 mm, and most preferably about 8.0 mm, 9.0 mm, 10.0 mm, 12.0 mm, or 14.0 mm; the posterior height being from about 7.0 mm to about 20.0 mm, preferably from about 8.0 mm to about 17.0 mm, more preferably from about 9.0 mm to about 15.0 mm, and most preferably the posterior height is about 7.0mm, 10.0 mm,11.0 mm, 12.0 mm, or 14.0 mm ; and the trapezoid wedge composite bone graft has a length of from about 15.0 mm to about 35.0 mm, preferably from about 17.0 mm to about 30.0 mm, more preferably from about 20.0 mm to about 27.0 mm, and most preferably a length of about 21.0 mm, or 23.0mm.

The bone portions may be interlocking and/or connected with one or more mechanical and/or chemical biocompatible connectors. The preferred connectors include mechanical connectors including for example, one or more cortical bone pins having a round cross-section and having a diameter of from about 1.0 mm to about 6.0 mm, preferably from about 2.0 mm to about 5.0 mm, more preferably from about 2.0 mm to about 4.5 mm, and most preferably a pin diameter of from about 2.0 mm to about 4.0 mm, where the diameter of each pin in a single graft may be the same or different. The diameter of the two corresponding through-holes is preferably sufficient to provide an interference or frictional or slidable connection between the bone portions and the pin, preferably a interference or frictional connection. The foregoing described trapezoid wedge composite optionally includes a cancellous bone portion disposed between the two cortical bone portions and having the same width or a greater width than the cortical bone portions. The trapezoid wedge composite graft can optionally include diametrically opposed chamfered edges.

Most preferable trapezoid wedge composite bone grafts include the following configurations:

(a) a first cortical portion having a width of from about 3.0mm to about 4.0 mm, preferably about 4.0 mm; a second cortical bone portion having a width of from about 3.0 mm to about 4.0 mm, preferably about 4.0 mm; a central cancellous bone portion having a width of from about 3.0 mm to about 5.0 mm, preferably about 3.0 mm disposed there between, forming a graft unit, the graft unit held together by two round cortical bone pins having a diameter of from about 2.0 mm to about 4.0 mm, the composite graft having an overall length of about 21.0 mm, an anterior height of about 9.0mm, and a posterior height of about 11.0 mm; or an anterior height of about 8.0 mm and a posterior height of about 10.0 mm, or an anterior height of about 10.0 mm and a posterior height of about 12.0 mm, or an anterior height of about 12.0 mm and a posterior height of about 14.0 mm.

(**b**) a first cortical portion having a width of about 4.0 mm; a second cortical bone portion having a width of about 4.0mm; a central cancellous bone portion having a width of about 3.0 mm disposed there between forming a graft unit, the graft unit held together by two round cortical bone pins having a diameter of about 3.0 mm, the composite graft having an overall length of about 21.0 mm, an anterior height of about 9.0 mm, and a posterior height of about 11.0 mm, or an anterior height of about 8.0 mm and a posterior height of about 10.0 mm, or an anterior height of about 10.0 mm and a posterior height of about 12.0 mm, or an anterior height of about 12.0 mm and a posterior height of about 14.0 mm; and where the length of the graft measured from the posterior end to the center of the first pin is about 5.5 mm, the length of the graft measured from the center point of a first pin to a center point of a second pin is about 8.0 mm and, the length of the graft measured from a center point of a second pin to the anterior end of the graft is about 7.5 mm, and optionally having opposing textured surfaces where the protrusions are in a saw-tooth pattern, and have a height of about 1.2 mm and have an angle of about 60° between protrusions;

(**c**) a first cortical portion having a width of about 3.0 mm; a second cortical bone portion having a width of about 3.0 mm; a central cancellous bone portion having a width of about 3.0 mm disposed there between forming a graft unit, the graft unit held together by two round cortical bone pins having a diameter of about 4.0 mm, the composite graft having an overall length of about 21.0 mm, an anterior height of about 7.0 mm, and a posterior height of about 9.0 mm, or an anterior height of about 8.0 mm and a posterior height of about 10.0 mm, or an anterior height of about 10.0 mm and a posterior height of about 12.0 mm, or an anterior height of about 12.0 mm and a posterior height of about 14.0 mm; and where the length of the graft measured from the posterior end to the center of the first pin is about 6.0 mm, the length of the graft measured from the center point of a

first pin to a center point of a second pin is about 9.0 mm and, the length of the graft measured from a center point of a second pin to the anterior end of the graft is about 6.0 mm, and optionally having opposing textured surfaces where the protrusions are in a saw-tooth pattern, and have a height of about 1.2 mm and have an angle of about 60° between protrusions;

(d) a first cortical portion having a width of about 3.0 mm, a second cortical bone portion having a width of about 3.0 mm, a central cancellous bone portion having a width of about 5.0 mm disposed there between, forming a graft unit, the graft unit held together by two round cortical bone pins having a diameter of about 2.0 mm to about 4.0 mm, the composite graft having an overall length of about 21.0 mm, an anterior height of about 9.0 mm, and a posterior height of about 11.0 mm;

(e) a first cortical portion having a width of about 3.0 mm, a second cortical bone portion having a width of about 3.0 mm, a central cancellous bone portion having a width of about 7.0 mm disposed there between, forming a graft unit, the graft unit held together by two round cortical bone pins having a diameter of about 2.0 mm to about 4.0 mm, the composite graft having an overall length of about 21.0 mm, an anterior height of about 11.0 mm, and a posterior height of about 13.0 mm;

(f) a first cortical portion having a width of about 3.0 mm, a second cortical bone portion having a width of about 3.0 mm, a central cancellous bone portion having a width of about 3.0 mm disposed there between, forming a graft unit, the graft unit held together by two round cortical bone pins having a diameter of about 2.0 to about 4.0 mm, the composite graft having an overall length of about 21.0 mm, an anterior height of about 7.0 mm, and a posterior height of about 9.0 mm;

(g) a first cortical portion having a width of about 4.0 mm, a second cortical bone portion having a width of about 4.0 mm forming a graft unit, the graft unit held together by two round cortical bone pins having a diameter of about 3.0 mm, the composite graft having an overall length of about 25.0 mm, an anterior height of about 12.0 mm, and a posterior height of about 15.0 mm;

(h) a first, second, third and fourth cortical bone portion each having a width of from about 2.0 mm to about 3.0 mm, preferably about 2.0 mm, a first cancellous bone portion having a width of from about 2.0 mm to about 3.0 mm, preferably about 3.0 mm, where the first cortical bone portion is disposed on the second cortical bone portion, the first cancellous bone portion is disposed between the second and third cortical bone portions, and the fourth cortical bone portion is disposed on the third cortical bone portion, forming a graft unit, the graft unit held together by two round cortical bone pins having a diameter of about 2.0 mm to about 4.0 mm, the composite graft having an overall length of about 21.0 mm, an anterior height of about 9.0 mm, a posterior height of about 11.0 mm, and a composite width of about 11.0 mm;

(i) a combination of at least two cortical bone portions optionally having a cancellous bone portion disposed therebetween, and having: **(1)** a posterior height of 9.0 mm an anterior height of 7.0 mm, a length of 21.0 mm, and a composite width of 12.0 mm; **(2)** a posterior height of 9.0 mm an anterior height of 7.0 mm, a length of 25.0 mm, and a composite width of 12.0 mm; **(3)** a posterior height of 11.0 mm, an anterior height of 9.0 mm, a length of 23.0 mm, and a composite width of 12.0 mm; **(4)** a posterior height of 11.0 mm, an anterior height of 9.0 mm, a length of 25.0 mm, and a composite width of 12.0 mm; **(5)** a posterior height of 13.0 mm, an anterior height of 11.0 mm, a length of 25.0 mm, and a composite width of 12.0 mm; and **(6)** a posterior height of 15.0 mm, an anterior height of 13.0 mm, a length of 25.0 mm, and a composite width of 12.0 mm; and

(j) a combination of two or more cortical bone portions optionally each having a patterned surface such that an interlocking fit between the bone portions is provided, and having: **(1)** a posterior height of 14.0 mm an anterior height of 10.0 mm, a length of 21.0 mm, and a composite width of 7.0 mm, two cortical bone pins each having a diameter of 3.0mm, and a slope of 10.8°, and having diametrically opposed chamfered edges at 45° and 0.5mm in depth, a distance from the center of the first pin to the center point of the second pin of 8.0mm, and a distance from the anterior end of the graft to the center point of the first pin of 7.5mm; **(2)** a posterior height of 12.0 mm an anterior height of 10.0 mm, a length of 21.0 mm, and a composite width of 7.0 mm, two cortical bone pins each having a diameter of 3.0mm, and a slope of 5.45°, having diametrically opposed chamfered edges at 45° and 0.5mm in depth, a distance from the center of the first pin to the second of the second pin of 8.0mm, and a distance from the anterior end of the graft to the center point of the first pin of 7.5mm; **(3)** a posterior height of 14.0 mm an anterior height of 12.0 mm, a length of 21.0 mm, and a composite width of 7.0 mm, two cortical bone pins each having a diameter of 3.0mm, and a slope of 5.45°, having diametrically opposed chamfered edges at 45° and 0.5mm in depth, a distance from the center of the first pin to the second of the second pin of 8.0mm, and a distance from the anterior end of the graft to the center point of the first pin of 7.5mm; **(4)** a posterior height of 11.0 mm, an anterior height of 9.0 mm, a length of 25.0 mm, and a composite width of 12.0 mm; **(5)** a posterior height of 12.0 mm an anterior height of 9.8mm, a length of 23.0 mm, and a composite width of 7.0 mm, two cortical bone pins each having a diameter of 3.0mm, and a slope of 5.5°, having diametrically opposed chamfered edges at 45° and 0.5mm in depth, a distance from the center point of the second pin to the posterior end of the graft of 13.5mm, and a distance from the center point of the first pin to the posterior end of the graft 5.5mm; **(6)** a posterior height of 14.0

mm an anterior height of 9.8mm, a length of 23.0 mm, and a composite width of 7.0 mm, two cortical bone pins each having a diameter of 3.0mm, and a slope of 10.8°, having diametrically opposed chamfered edges at 45° and 0.5mm in depth, a distance from the center point of the second pin to the posterior end of the graft of 13.5mm, and a distance from the center point of the first pin to the posterior end of the graft 5.5mm; **(7)** a posterior height of 13.0 mm an anterior height of 9.0mm, a length of 23.0 mm, and a composite width of 7.0 mm, two cortical bone pins each having a diameter of 3.0mm, and a slope of 10.8°, having diametrically opposed chamfered edges at 45° and 0.5mm in depth, a distance from the center point of the second pin to the posterior end of the graft of 13.5mm, and a distance from the center point of the first pin to the posterior end of the graft of 5.5mm; **(8)** a posterior height of 13.0 mm an anterior height of 11.0mm, a length of 23.0 mm, and a composite width of 7.0 mm, two cortical bone pins each having a diameter of 3.0mm, and a slope of 5.4°, having diametrically opposed chamfered edges at 45° and 0.5mm in depth, a distance from the center point of the second pin to the posterior end of the graft of 13.5mm, and a distance from the center point of the first pin to the posterior end of the graft 5.5mm; **(9)** a posterior height of 11.0 mm an anterior height of 9.0mm, a length of 23.0 mm, and a composite width of 7.0 mm, two cortical bone pins each having a diameter of 3.0mm, and a slope of 5.4°, having diametrically opposed chamfered edges at 45° and 0.5mm in depth, a distance from the center point of the second pin to the posterior end of the graft of 13.5mm, and a distance from the center point of the first pin to the posterior end of the graft of 5.5mm; **(10)** a posterior height of 7.0 mm an anterior height of 5.0mm, a length of 21.0 mm, two cortical bone pins, and optionally having diametrically opposed chamfered edges; **(11)** a posterior height of 7.0 mm an anterior height of 5.0mm, a length of 23.0 mm, two cortical bone pins and optionally having diametrically opposed chamfered edges; and **(12)**

a posterior height of 7.0 mm an anterior height of 5.0mm, a length of 25.0 mm, two cortical bone pins, and optionally having diametrically opposed chamfered edges.

The composite bone grafts having a parallel block shape and optionally having opposing textured surfaces disposed perpendicular to the interfaces of the bone portions, and optionally having diametrically opposed chamfered edges, preferably include: a combination of two or more bone portions, preferably cortical bone portions, optionally each having a patterned surface such that an interlocking fit between adjacent bone portions is provided; and: **(a)** at least two cortical bone portions each having a width of from about 1.5 mm to about 10.0 mm, preferably from about 2.0 mm to about 7.0 mm, more preferably from about 3.0 mm to about 5.0 mm, and most preferably having a width of about 4.0 mm to give a composite width of about 15.0 mm; the parallel block composite bone graft has a height from about 5.0 mm to about 20.0 mm, preferably from about 7.0 mm to about 19.0 mm, more preferably from about 8.0 mm to about 17.0 mm, and most preferably from about 9.0 mm to about 16.0 mm; and the parallel block composite bone graft has a length of from about 15.0 mm to about 35.0 mm, preferably from about 17.0 mm to about 30.0 mm, more preferably from about 20.0 mm to about 27.0 mm, and most preferably a length of from about 21.0 mm to about 25.0mm. The preferred mechanical connectors include one or more, preferably two cortical bone pins having a round cross-section and having a diameter of from about 1.0 mm to about 6.0 mm, preferably from about 2.0 mm to about 5.0 mm, more preferably from about 2.5 mm to about 4.5 mm, and most preferably a pin diameter of from about 3.0 mm to about 4.0 mm, where the diameter of each cortical bone pin may be the same of different.. The diameter of the two corresponding through-holes is preferably sufficient to provide an interference or frictional or slidable connection between the bone portions and the pin, preferably a interference or frictional connection, and

(b) two or more cortical bone portions layered to form a graft unit, and optionally one or more cancellous bone portions disposed between said cortical bone portions, the graft unit being connected by one or more mechanical connectors, preferably two cortical bone pins having a diameter of from about 1.0 mm to about 6.0 mm, preferably from about 2.0 mm to about 5.0 mm, more preferably from about 2.5 mm to about 4.5 mm, and most preferably a pin diameter of from about 3.0 mm to about 4.0 mm, where the diameter of each pin may be the same or different, and having a composite width of from 4.5 mm to about 30.0 mm, preferably from about 6.0 mm to about 21.0 mm, more preferably from about 9.0 mm to about 15.0 mm, and most preferably having a width of about 4.0 mm to give a composite width of about 12.0 mm to about 15.0 mm, a posterior and anterior height of from about 5.0 m to about 20.0 mm, preferably from about 9.0 mm to about 17.0 mm, and a length of from about 20.0 mm to about 30.0 mm, specific preferred configurations include the following: following configurations: **(1)** an anterior and posterior height of about 9.0 mm, and a length of about 25.0 mm; **(2)** an anterior and posterior height of about 9.0 mm, and a length of about 21.0 mm; **(3)** an anterior and posterior height of about11.0 mm, and a length of about 25.0 mm; **(4)** an anterior and posterior height of about 11.0 mm, and a length of about 21.0 mm; **(5)** an anterior and posterior height of about 13.0 mm, and a length of about 25.0 mm; **(6)** an anterior and posterior height of about 11.0 mm, and a length of about 23.0 mm; **(7)** an anterior and posterior height of about 13.0mm, and a length of about 23.0 mm; **(8)** an anterior and posterior height of about 15.0 mm, and a length of about 25.0 mm; and **(9)** an anterior and posterior height of about 17.0 mm, and a length of about 25.0 mm. The foregoing described parallel block composite bone graft optionally includes a cancellous bone portion disposed between the two cortical bone portions and having the same width or a greater width than the cortical bone portions.

Most preferable parallel block composite bone grafts include the following configurations: **(a)** two or more cortical bone portions having a composite width of about 15.0 mm, held together by two round cortical bone pins having a diameter of about 2.0 mm to about 4.0 mm, where each pin has the same or a different diameter, the composite graft having a height of about 16.0 mm and a length of about 25.0 mm,

(b) a first cortical portion having a width of about 3.0 mm, a second cortical bone portion having a width of about 3.0 mm, one or more central cancellous bone portions having a composite width of about 9.0 mm disposed there between, forming a graft unit, the graft unit held together by two round cortical bone pins having a diameter of about 2.0 mm to about 4.0 mm, where the diameter of each pin is the same or different, the composite graft having a height of about 16.0 mm and an overall length of about 25.0 mm, the parallel block composite bone graft also includes opposing textured surfaces disposed perpendicular to the interfaces of the bone portions;

(c) a first cortical bone portion having a width of about 3.0 mm, a second cortical bone portion having a width of about 3.0 mm, a central cancellous bone portion having a width of about 3.0 mm disposed there between, forming a graft unit, the graft unit held together by two round cortical bone pins having a diameter of about 2.0 mm to about 4.0 mm, where the diameter of each bone pin is the same or different, the composite graft having a height of about 10.0 mm and a length of about 25.0 mm, the parallel block composite bone graft also includes opposing textured surfaces disposed perpendicular to the interfaces of the bone portions;

(d) a first cortical portion having a width of about 3.0 mm, a second cortical bone portion having a width of about 3.0 mm, a central cancellous bone portion having a width of about 3.0 mm disposed there between, forming a graft unit, the graft unit held together by two round cortical bone

pins having a diameter of about 2.0 mm to about 4.0 mm, where the diameter is the same or different, the composite graft having a height of about 9.0 mm and a length of about 21.0 mm,

(e) a first cortical portion having a width of about 3.0 mm, a second cortical bone portion having a width of about 3.0 mm, a central cancellous bone portion having a width of about 5.0 mm disposed there between, forming a graft unit, the graft unit held together by two round cortical bone pins having a diameter of about 2.0 mm to about 4.0 mm, Where the diameter of each bone pin is the same or different, the composite graft having a height of about 11.0 mm and a length of about 21.0 mm, and

(f) a first cortical portion having a width of about 3.0 mm, a second cortical bone portion having a width of about 3.0 mm, a central cancellous bone portion having a width of about 7.0 mm disposed there between, forming a graft unit, the graft unit held together by two round cortical bone pins having a diameter of about 2.0 mm to about 4.0 mm, where the diameter of each bone pin is the same or different, the composite graft having a height of about 13.0 mm and a length of about 21.0 mm.

Most preferable cortical block composite bone grafts include the following configurations: **(a)** a plurality of cortical bone portions each having a width of from about 3.0 mm to about 4.0 mm, preferably about 3.0 mm and the plurality of cortical bone portions having a composite width of from about 18.0 to about 22.0 mm, preferably a composite width of about 20.0 mm, the cortical block composite has a height of from about 18.0 to about 22.0 mm, preferably of about 20.0 mm and a length of from about 18.0 to about 22.0 mm, preferably of about 20.0 mm or 21.0 mm, with the graft unit held together by two round cortical bone pins having a diameter of about 2.0 mm to about 4.0 mm, where the diameter of each pin is the same or different, and **(b)** the cortical block composite

bone graft of (a) where one or more of the central cortical bone portions are replaced with one or more cancellous bone portions having an overall width of from about 3.0 to about 15.0 mm, preferably about 14.0 mm.

Most preferable cervical wedge grafts (flattened curved wedge composite bone grafts) for cervical fusion, include the following configurations: a combination of two or more cortical bone portions optionally each having a patterned surface such that an interlocking fit between the bone portions is provided, and: **(a)** a first cervical (flattened curved) cortical portion having a width of from about 2.0 mm to about 8.0 mm; a second cervical cortical bone portion having a width of from about 2.0 mm to about 8.0 mm; where the first portion is disposed on the second portion forming a graft unit, the graft unit is held together by at least two cortical bone pins having a diameter of from about 2.0 mm to about 4.0 mm, preferably 2.0 mm to about 3.0 mm; where the diameter of each pin is the same or different, the composite graft having a width of about 10.0 to about 20.0 mm, preferably about 16.0 mm, a diameter of about 10.0 mm to about 18.0 mm, preferably about 13.0 mm, and a centrally located hole, preferably from about 2.0 to about 8.0 mm in diameter, more preferably from about 3.0 to about 5.0 mm in diameter, disposed through the pinned graft unit, between at least two pins. Each of the top and bottom surfaces of the cervical fusion graft, from a side view, may be sloped at an angle of from about 0° to about 15°, preferably at an angle of from about 3° to about 10°, and most preferably one of the top or bottom surfaces sloped at an angle of about 7° with the other surface not sloped, along the top and bottom faces of the graft from the curved top end to the flattened bottom end as shown in Figures 14 and 15, to form the wedge shape.

The anterior composite width at the flattened end is preferably from about 6.0 to about 8.0 mm. The top and bottom opposing faces of the cervical graft may optionally be textured, preferably with a plurality of pyrimidal protrusions,

(b) a first cervical (flattened curved) cortical portion having a width of from about 2.0 mm to about 8.0 mm; a second cervical cortical bone portion having a width of from about 2.0 mm to about 8.0 mm; where the first portion is disposed on the second portion forming a graft unit, the graft unit is held together by at least two cortical bone pins having a diameter of from about 2.0 mm to about 4.0 mm, preferably 2.0 mm to about 3.0 mm; where the diameter of each pin may be the same or different, the composite graft having a width of about 15.0 to about 25.0 mm, preferably about 19.0 mm, a diameter of about 12.0 mm to about 20.0 mm, preferably about 15.0 mm, and a centrally located hole disposed through the pinned graft unit, between at least two pins. The cervical fusion graft, from a side view, is preferably sloped at an angle of from about 3° to about 15°, preferably at an angle of about 7° along the top and bottom faces, or an angle of 0° along the top surface and an angle of 7° along the bottom surface, of the graft from the curved end to the flattened end as shown in Figures 14 and 15, to form the wedge shape. The anterior composite width at the flattened end is preferably from about 6.0 to about 8.0 mm. The top and bottom opposing faces of the cervical graft may optionally be textured, preferably with a plurality of pyrimidal protrusions,

(c) a first and a second cervical (flattened curved) cortical bone portion, the first bone portion disposed on the second bone portion to form a graft unit, the graft unit is held together by at least two cortical bone pins having a diameter of from about 2.0 mm to about 4.0 mm, and having the following preferred configurations: a posterior composite width of from 5.0 mm to 15.0 mm, preferably from about 8.0 mm to 10.0 mm, an anterior composite width of from about 5.0 mm to

about 10.0 mm, preferably from about 6.0 mm to about 8.0 mm, ; the composite graft having a width of from about 12.0 to about 25.0 mm, preferably from about 16.0 mm to about 19.0 mm, a diameter of from about 10.0 mm to about 20.0 mm, preferably from about 13.0 mm to about 15.0 mm, and a centrally located hole disposed through the pinned graft unit, between at least two pins. The graft, from a side view, is preferably sloped at an angle of from about 3° to about 15°, preferably at an angle of about 7°, or an angle of 0° along the top surface and an angle of 7° along the bottom surface, along the top and bottom faces of the graft from the curved end to the flattened end as shown in Figures 14 and 15, to form the wedge shape. The top and bottom opposing faces of the cervical graft may optionally be textured, preferably with a plurality of pyrimidal protrusions; and

(d) two or more bone portions preferably cortical bone portions, layered to form a graft unit, where the bone portions are connected by: being configured to interlock with each other where the interlocking is self-locking or is locked with one or more pins entirely or partially traversing a dimension of the graft, and/or at least two cortical bone pins having a diameter of from about 2.0mm to about 4.0mm and having the following preferred configurations: **(I)** a diameter of about 14.0mm; a width of about 17.5mm; a pin diameter of about 2.5mm; a through-hole having a diameter of about 6.5mm, a first width of about 9.0mm, and a second width of about 4.0mm; a distance from the arc to a pin and from the through-hole to the second width of the graft, of about 2.0mm; a second width of about 10.0mm, and the graft having its sides sloped at an angle of about 25° (see fig. 44); and **(ii)** a diameter of about 12.0mm; a width of about 14.5mm; a pin diameter of about 2.5mm; a through-

hole having a diameter of about 4.0mm; a distance from the arc to a pin and from the through-hole to the second width of the graft, and from the pin to the through-hole, of about 2.0mm; a second width of about 7.75mm, and the graft having its sides sloped at an angle of about 25° (see fig. 43).

Most preferable anterior lumbar oval wedge composite bone grafts include the following configurations: **(a)** two or more ovoid cortical bone portions disposed on each other thereby forming a graft unit having a composite posterior width of from about 5.0 mm to about 20.0 mm, preferably from about 1.0 mm to about 15.0 mm, an anterior composite width of from 5.0 mm to about 20.0 mm, preferably from about 8.0 mm to about 14.0 mm, a height of from about 15.0 mm to about 30.0 mm, preferably from about 21.0 mm to about 28.0 mm, and a length of from about 23.0 mm to about 45.0 mm, preferably from about 32.0 mm to about 42.0 mm; the graft unit is held together by at least two cortical bone pins having a diameter of from about 2.0 mm to about 4.0 mm, where the pins have the same or a different diameter, to form a pinned graft unit; and optionally one or more through- holes disposed through the pinned graft unit. The graft, from a side view, is preferably sloped at an angle of from about 3° to about 15°, preferably at an angle of about 7°, or an angle of 0° along the top surface and an angle of 7° along the bottom surface, along the top and bottom faces of the to form the wedge shape. The top and bottom opposing faces of the cervical graft may optionally be textured.

Any one or more of the cortical and/or cancellous bone portions of the above-described composite bone grafts, may optionally be demineralized and/or discontinuous, depending upon the particular clinical application. For example, any one or more bone portions of any composite graft may include for example, one or more horizontally disposed channels, vertically disposed channels or randomly disposed channels, partially or completely traversing the height and/or width of the

graft. One of ordinary skill in the art to which the present invention pertains can readily select, make and employ, a particular composite graft, without undue experimentation.

V. Surgical Implantation and Indications

The present composite bone graft is useful for implantation in patients suffering from defects caused by congenital anomaly, disease, or trauma, including for example, spine fractures; deformity, e.g. kyphotic deformities, e.g. posttraumatic kyphosis; postlaminectomy kyphosis, junctional kyphosis, and Scheuermann's kyphosis; scoliosis, e.g. neuromuscular scoliosis, adult scoliosis, paralytic scoliosis, congenital and syndromic scoliosis; and cervical neck pain. Surgical methods for correcting degenerative conditions, for example in the lumbar spine, include decompression (excision of disc material, hypertrophied bone, or ligament along with fusion, or fusion alone.

A posterior surgical approach is preferably used. The choice of approach is dictated by the site of primary pathology and the physical size of the composite bone graft. Pathology that involves vertebral bodies is best approached anteriorly through the thorax, abdomen or flank. Pathology involving posterior elements are best approached posteriorly for example, through a vertical midline approach or posterior lateral muscle spinning approach.

Those of ordinary skill in the art to which the present invention pertain, including for example an orthopaedic surgeon and a spinal surgeon, can readily select and employ a particular composite bone graft, without undue experimentation. Factors to be considered in such selection and employment include: the type and size of graft bone, its anatomic site of fusion, and the age of the patient. An ideal graft, for example for use in lumbar interbody fusion, should be: osteoinductive, non-immunogenic, provide immediate mechanical stability, and be appropriately

sized and shaped for the particular application/patient. Indications, diagnostic criteria, graft selection and surgical technique, are factors that can be readily selected, optimized and employed by those of ordinary skill in the art without undue experimentation, and are discussed in: Master Techniques in Orthopaedic Surgery, ***The Spine***, edited by Bradford, David S., Lippincott-Raven, ISBN 0-7817-0033-7, Philadelphia, PA, (1997), hereby incorporated herein by reference in its entirety. When implanting a cervical fusion graft, an anterior cervical approach is used.

The following examples are illustrative only, and do not in any way limit the scope of the invention.

EXAMPLES

I. Preparation of a composite graft.

Donor bone was harvested according to industry accepted standards from a cadaver donor. The composite bone grafts, sized as recorded in Table 1, were prepared according to the method described as follows. Using a bandsaw cortical planks and pin segments were cut from a cortical shaft. One surface of each cortical planks was smoothed on a planing table and the planks were cut to the recorded thickness using a mill. Thereafter, using a table saw, the cut planks were cut to the recorded width and length. Cortical pins were then cut using a drill press, from the pin segments. Using a drill sander, the cortical pins were tapered sufficient to allow insertion into the reamed graft unit. Next, using a bandsaw, cancellous wafers were cut from cancellous bone to the recorded thickness. The wafers were then cut to the recorded width and length using a table saw. The cortical planks and cancellous wafer were then assembled into a graft unit in a jig and were then reamed using a drill press. The anterior through-hole was disposed through the width of the graft unit at the

through-hole's center point, 7.5 mm along the length of the graft unit, and centered relative to the width of the graft unit. Using an arbor press, the cortical pins were pushed into the reamed graft unit to produce a pinned graft unit. Any excess pin was then cut off using a bandsaw. Next, using a drill sander, the pinned graft unit was then shaped to the final recorded width, and if the composite graft was angled, the pinned graft was then milled to cut angles. The composite graft was milled to provide grooves of the recorded height, on the opposing surfaces as shown in the Figures. The produced composite bone grafts were then cleaned and tested as follows.

TABLE 1

Specimen number	Graft Type	Composite width (mm)	Tooth (mm) Height	Tooth angle	Composite Height (mm) front	Composite Height (mm) back	Length (mm)	Pins (mm) front	Pins (mm) back	Cancellous* width (mm)	Cortical* width (mm)
1	trapezoid wedge(TA)	9.0	1.2	60.0°	8.0	10.0	21.0	2.5	3.0	3.0	3.0
2	trapezoid wedge(TB)	11.0	1.5	60.0°	10.0	12.0	21.0	3.0	3.0	5.0	3.0
3	trapezoid wedge(TC)	13.0	1.5	60.0°	12.0	14.0	21.0	3.0	3.0	5.0	4.0
4	trapezoid wedge(TD)	13.0	1.5	60.0°	12.0	14.0	21.0	3.0	3.0	5.0	4.0**
5	parallel block(PA)	7.0	1.2	60.0°	9.0	9.0	21.0	2.5	2.5	3.0	2.0
6	parallel block(PB)	9.0	1.2	60.0°	9.0	9.0	21.0	2.5	2.5	3.0	3.0
7	parallel block(PC)	9.0	1.2	60.0°	11.0	11.0	21.0	3.0	3.0	3.0	3.0
8	parallel block(PD)	9.0	1.2	60.0°	10.0	10.0	21.0	2.5	3.0	3.0	3.0
9	parallel block(PE)	11.0	1.5	60.0°	13.0	13.0	21.0	3.0	3.0	5.0	3.0
10	parallel block(PF)	11.0	1.5	60.0°	12.0	12.0	21.0	3.0	3.0	5.0	3.0
12	parallel block(PG)	13.0	1.5	60.0°	14.0	14.0	21.0	3.0	3.0	5.0	4.0**
11	parallel block(PH)	11.0	–	–	9.0	9.0	21.0	3.0	3.0	5.0	3.0
12	parallel block(PI)	11.0	–	–	9.0	9.0	21.0	3.0	3.0	3.0	4.0**
13	parallel block(PJ)	9.0	–	–	7.0	7.0	21.0	2.5	2.5	3.0	3.0

* +0.500 mm or – 0.250 mm

** two (2) cortical planks were used, each ~2.0 mm to give a composite cortical width of 4.0 mm

II. Biomechanical Strength

The biomechanical strength of the composite bone grafts recorded in Table 2 was determined using static compression testing. All of the tested bone grafts were produced as set forth in Example

1, and sized as recorded. All of the composite bone grafts were constructed from two cortical layers sandwiching a cancellous layer with all of the layers oriented parallel to the sagittal plane, and secured together with two cortical bone pins. Tests were performed under a compressive load using an Instron™ 4204 test machine. An axial displacement was applied in a ramp fashion at 2.5 mm/min rate until catastrophic failure of the bone graft occurred or until the maximum displacement of 3 mm was reached. Data was collected at a rate of 2 Hz.

As can be seen from the data set forth in Table 2, all of the composite grafts exhibited adequate to exceptional biomechanical strength, as compared to the vertebral body itself which fails at 10,000 N (2,200 lbs).

TABLE 2

Graft Type	Specimen number	Load at Max. Load (KN)	Displacement at Max. Load (Mm)	Load at z-slp, yield (Mm)	Displacement at z-slp, yield (Mm)	Stiffness (slope) (AutYoung) (N/mm)
PA	PA-1	8.464	3.460	6.719	1.706	6708.0
(Donor 1)	PA-2	8.923	2.450	8.625	1.957	6544.0
	PA-3	8.569	3.020	7.323	1.851	6201.0
	PA-4	7.238	3.070	6.727	1.998	4756.0
	PA-5	8.395	2.160	8.078	1.873	7321.0
Mean (Donor 1):		8.318	2.832	7.495	1.877	6306
Std. Dev (Donor 1):		.637	.521	.842	.113	957
(Donor 2)	PA-6	9.718	3.300	6.636	1.560	5637.0
	PA-7	8.118	1.970	8.113	1.956	6379.0
	PA-8	11.190	3.150	9.052	2.102	6246.0
	PA-9	8.201	2.110	8.193	2.102	6643.0
	PA-10	5.992	1.430	5.882	1.248	7973.0
	PA-11	7.248	2.500	7.130	2.060	6578.0
	PA-12	8.319	2.660	8.228	2.123	6500.0
	PA-13	6.325	2.690	5.782	1.624	4518.0
	PA-14	7.973	1.770	7.970	1.749	5867.0
	PA-15	8.969	2.750	–	–	5546.0
Mean (Donor 2):		8.205	2.433	–	–	6189.0
Std. Dev. (Donor 2):		1.535	.601	–	–	900.0
(Donor 3)	PA-16	7.259	1.540	7.256	1.541	8207.0
(Donor 4)	PA-17	9.799	1.710	9.799	1.687	9930.0
	PA-18	7.879	1.640	7.876	1.623	7963.0
	PA-19	9.590	1.620	9.584	1.603	9794.0
	PA-20	9.388	1.670	9.380	1.665	8773.0
	PA-21	9.617	1.750	9.617	1.748	10260.0
Mean (Donor 4):		9.255	1.678	9.251	1.655	9344.0
Std. Dev. (Donor 4)		.783	.053	.783	.057	950
PC	PC-1	9.165	4.000	7.216	1.811	10230.0
(Donor 5)	PC-2	7.664	2.860	7.664	2.853	4291.0
	PC-3	8.360	2.810	8.338	2.791	4226.0
	PC-4	8.612	.970	8.607	.958	19260.0
Mean (Donor 5):		8.450	2.660	7.956	2.103	9503.0
Std. Dev. (Donor 5):		.623	1.254	.633	.900	7090.0
(Donor 6)	PC-5	10.45	2.040	10.36	1.540	9482.0
	PC-6	10.17	2.140	10.17	2.144	7261.0
	PC-7	11.74	2.090	11.73	2.060	10330.0
	PC-8	11.77	2.290	11.76	2.290	9123.0
Mean (Donor 6):		11.03	2.140	11.01	2.009	9049.0
Std. Dev. (Donor 6):		.84	.108	.86	.326	1295.0

TABLE 2 ***(cont.)***

Graft Type	Specimen number	Load at Max. Load (KN)	Displacement at Max. Load (Mm)	Load at z-slp, yield (Mm)	Displacement at z-slp, yield (Mm)	Stiffness (slope) (AutYoung) (N/mm)
PB	PB-1	8.953	1.540	8.604	1.310	10160.0
(Donor 7)	PB-2	10.910	1.850	10.910	1.852	10380.0
Mean (Donor 7):		9.931	1.695	9.758	1.581	10270.0
Std. Dev. (Donor 7):		1.336	.219	1.632	.383	156.0
PE (Donor 8)	PE-1	11.42	1.810	11.21	1.601	13900.0

III. Comparative Biomechanical Strength

Composite bone grafts were produced as described in Example A. 11 x 9 x 21 mm grafts: (PH) having two 3.0 mm cortical layers sandwiching a 5.0 mm cancellous layer, and (PI) having two 4.0 mm cortical layers sandwiching a 3.0 mm cancellous layer; and 9 x 7 x 21 mm grafts (PJ) having two 3.0 mm cortical layers sandwiching a 3.0 mm cancellous layer, were produced. After production, the grafts were either fresh frozen or freeze-dried. Table 3 summarizes the compression test results of fresh frozen composite grafts after thawing in 9.0 % saline solution for 90 minutes and the freeze-dried composite bone grafts after soaking for 20 min., 60 min., and 7 days in 9.0 % saline solution.

Test results showed that the 20 minute soaked freeze- dried grafts had the highest strength (Table 3) and stiffness (Table 4) among all the tested groups. Generally, strength and stiffness of the fresh-frozen grafts were relatively lower than the freeze-dried grafts.

The inventive composite bone graft, both fresh-frozen and freeze-dried, when compared to commercially available bone graft products (Os™ and Mid America) was significantly stronger. See *Brantigan et al*, Compression Strength of Donor Bone for Posterior Lumbar Interbody Fusion, Spine Vol. 18, No. 9, 1993.

TABLE 3

Graft Type	Specimen Number 1	2	3	4	5	Mean	Std. Dev.
Fresh Frozen-one-hour (PH-1)	9.114	9.160	6.942	6.945	9.852	**8.403**	1.364
Fresh Frozen-one-hour (PH-2)	9.176	8.744	–	–	–	**8.960**	0.305
Freeze-dried-20.0 min. (PI-1)	13.970	14 460	–	–	–	**14.220**	0.346
Freeze-dried-one-hour (PI-2)	13.99	13.97	–	–	–	**13.98**	0.014
Freeze-dried-seven-days (PI-3)	10.300	8.255	–	–	–	**9.277**	1.446
Fresh Frozen-one-hour (PJ-1)	7.925	7.973	8.958	7.836	9.799	**8.498**	.985
Fresh Frozen-one-hour (PJ-2)	8.897	9.015	–	–	–	**8.956**	.083
Os™ •	1.098	.934	5.72	2.145	–	**2.474**	2.229
Mid America Tricortical ••	2.823	1.699	1.926	2.629	2.464	**2.308**	0.477

• Os™ bone is a commercial tricortical bone graft product.

• •Mid America tricortical is a commercially available bone graft product produced by Mid America.

TABLE 4

Graft Type	Specimen Number 1	2	3	4	5	Mean	Std. Dev.
Fresh Frozen-one-hour (PJ-1) (9x7, 3-3-3)	7053.0	6176.0	5878.0	5434.0	7528.0	**6413.8**	1103.4
Fresh Frozen-one-hour (PJ-2) (9x7, 3-3-3)	7303.0	6112.0	–	–	–	**6707.5**	842.2
Fresh Frozen-one-hour (PH-1) (11x9, 3-5-3)	10980.0	13900.0	–	–	–	**12440.0**	2064.8
Fresh Frozen-one-hour (PH-2) (11x9, 3-5-3)	4938.0	11340.0	11060.0	12180.0	9125.0	**9728.0**	2902.3
Freeze-dried-20.0 min. (PI-1) (11x9, 4-3-4)	27760.0	28420.0	–	–	–	**28090.0**	466.7
Freeze-dried-one-hour (PI-2) (11x9, 4-3-4)	21940.0	22890.0	–	–	–	**22415.0**	671.8
Freeze-dried-seven-days (PI-3) (11x9, 4-3-4)	14590.0	18130.0	–	–	–	**16360.0**	2503.2

IV. Preparation of a cervical wedge composite graft.

Donor bone was harvested according to industry accepted standards from a cadaver donor. The composite bone grafts, sized as recorded in Table 5, were prepared according to the method described as follows. Using a bandsaw cortical planks and pin segments were cut from a cortical shaft. One surface of each cortical planks was smoothed on a planing table and the planks were cut to the required thickness using a mill. Thereafter, using a table saw, the cut planks were cut to the required width and length. Cortical pins were then cut using a drill press, from the pin segments. Using a drill sander, the cortical pins were tapered sufficient to allow insertion into the reamed graft unit. Next, the cortical planks were assembled into a graft unit in a jig and were then reamed using a drill press. Using an arbor press, the cortical pins were pushed into the reamed graft unit to produce a pinned unit. At this point, the pinned unit was optionally sloped at it's top and/or bottom

surface, for example at its bottom surface, at 7° using a radial saw. A circular shape was then cut through the pinned and optionally sloped unit using a trephine or Cloward cutter of appropriate size. Thereafter, using a radial saw or a band saw, the sides and bottom of the graft were shaped, and a centrally located hole was drilled through the pinned unit. Any excess pin was then cut off using a bandsaw. Lastly, the pinned graft unit was smoothed. If textured, the composite graft was milled to provide grooves on the opposing surfaces as shown in Figure 35.

TABLE 5

Specimen number	Graft Type	Composite Width(mm) Front	back	Diameter (Mm)	Width (Mm)
1	Cervical Wedge (CA)	6.0	10.0	13.0	16.0
2	Cervical Wedge (CB)	7.0	11.0	13.0	16.0
3	Cervical Wedge (CC)	8.0	12.0	13.0	16.0
4.	Cervical Wedge (CD)	6.0	10.0	15.0	19.0
5.	Cervical Wedge (CE)	7.0	11.0	15.0	19.0
6.	Cervical Wedge (CF)	8.0	12.0	15.0	19.0
7.	Cervical Wedge (CG)	6.0	6.0	13.0	16.0
8.	Cervical Wedge (CH)	8.0	8.0	13.0	16.0
9.	Cervical Wedge (CI)	6.0	6.0	15.0	19.0
10.	Cervical Wedge (CJ)	7.0	7.0	13.0	16.0
11.	Cervical Wedge (CK)	7.0	7.0	15.0	19.0

It is to be understood, however, that the scope of the present invention is not to be limited to the specific embodiments described above. The invention may be practiced other than as particularly described and still be within the scope of the accompanying claims.

WE CLAIM:

1. A composite bone graft, comprising: a plurality of bone portions layered to form a graft unit, and one or more biocompatible connectors for holding together said graft unit, said biocompatible connectors do not comprise an adhesive.

2. A composite bone graft comprising:

two or more distinct bone portions, and

one or more biocompatible connectors, wherein said biocompatible connectors hold together said two or more bone portions to form said composite bone graft, said biocompatible connectors do not comprise an adhesive.

3. A composite bone graft comprising two or more connected, distinct, bone portions, said connected, distinct, bone portions do not comprise an adhesive.

4. A composite bone graft comprising three or more connected, distinct, bone portions, said connected, distinct, bone portions are not connected with an adhesive.

5. The composite bone graft of any one of claims 1 or 2, said bone portions are selected from the group consisting of: cortical bone and cancellous bone.

6. A composite bone graft, comprising:

a first bone portion;

a second bone portion;

a third bone portion, said first, second and third bone portions are layered to form a graft unit; and

one or more biocompatible connectors for holding together said graft unit, said biocompatible connectors do not comprise an adhesive.

7. A composite bone graft, comprising:

a first cortical bone portion;

a second cortical bone portion;

a cancellous bone portion disposed between said first cortical bone portion and said second cortical bone portion to form a graft unit; and

one or more biocompatible connectors for holding together said graft unit, said biocompatible connectors do not comprise an adhesive.

8. A composite bone graft, comprising:

a first cortical bone portion;

a second cortical bone portion provided on said first cortical bone to form a graft unit; and

one or more biocompatible connectors, connecting said graft unit, said biocompatible connectors do not comprise an adhesive.

9. A composite bone graft, comprising:

a first bone portion;

a second bone portion provided on said first bone portion to form a graft unit; and

one or more biocompatible connectors for holding together said graft unit, said biocompatible connectors do not comprise an adhesive.

10. A composite bone graft, comprising: a plurality of cortical bone portions layered to form a graft unit, and one or more biocompatible connectors for holding together said graft unit, said biocompatible connectors do not comprise an adhesive.

11. A composite bone graft, comprising:

one or more cortical bone portions layered to form a first unit;

one or more cortical bone portions layered to form a second unit;

one or more cancellous bone portions layered to form a third unit; said third unit disposed between said first unit and said second unit to form a graft unit; and

one or more biocompatible connectors for holding together said graft unit, said biocompatible connectors do not comprise an adhesive.

12. The composite bone graft of any one of claims 1, 2, or 11, said biocompatible connectors comprising one or more mechanical biocompatible connectors.

13. The composite bone graft of any one of claims 1, 2, or 11, said biocompatible connectors comprising a chemical biocompatible connector, said chemical biocompatible connector does not comprise an adhesive.

14. The composite bone graft of claim 12, said mechanical biocompatible connectors comprise one or more pins.

15. The composite bone graft of claim 12, wherein said mechanical biocompatible connectors comprise one or more biocompatible materials selected from the group consisting of: cortical bone; stainless steel; titanium; cobalt-chromium-molybdenum alloy; a plastic of one or more members selected from the group consisting of: nylon, polycarbonate, polypropylene, polyacetal, polyethylene, and polysulfone; and one or more bioabsorbable polymers.

16. The composite bone graft of any one of claims 1-4, 6-9, or 10, said bone portions are configured to provide an interlocking fit between adjacent bone portions.

17. The composite bone graft of claim 15, said one or more bioabsorbable polymers selected from the group consisting of: poly(galatic acid), poly(latic acid) and copolymers thereof.

18. The composite bone graft of claim 15, said mechanical biocompatible connector further comprising one or more therapeutically beneficial agents.

19. The composite bone graft of claim 18, said therapeutically beneficial agents selected from the group consisting of: an osteoinductive substance, an anti-inflammatory agent, an antibiotic, a growth factor, and a chemotherapeutic substance.

20. The composite bone graft of claim15, wherein said one or more mechanical biocompatible connectors comprise cortical bone.

21. The composite bone graft of claim 20, wherein cortical bone mechanical connectors comprises one or more cortical bone pins.

22. The composite bone graft of claim 14, wherein said one or more pins comprise one or more cortical bone pins.

23. The composite bone graft of any one of claims 14, 21, or 22, wherein said graft unit comprises one or more through-holes configured to accomadate said one or more pins.

24. The composite bone graft of claim 23, said through-holes are disposed perpendicular to interfaces of bone portions of said graft unit.

25. The composite bone graft of claim 24, wherein said one or more pins and said through-holes are configured to provide an interference fit for holding together said graft unit.

26. The composite bone graft of claim 25, wherein said one or more through-holes and said one or more pins are round and an inner diameter of a through-hole is smaller than a diameter of a pin, to provide an interference fit between said through-hole and said pin.

27. The composite bone graft of claim 21, said one or more cortical bone pins comprising a plurality of vertical groves provided on a surface thereof.

28. The composite bone graft of claim 21, said one or more cortical bone pins comprising a roughened surface.

29. The composite bone graft of claim 21, said one or more cortical bone pins further comprising a slot extending from one end of said bone pin.

30. The composite bone graft of claim 22, said one or more cortical bone pins further comprising a slot extending from one end of said bone pin.

31. The composite bone graft of claim 23, wherein said one or more pins is threaded to provide a threaded engagement with said one or more through-holes.

32. The composite bone graft of claim 31, wherein said one or more pins is threaded and said one or more through-holes is threaded, to provide a threaded engagement between said one or more pins and said one or more through-holes.

33. The composite bone graft of claim 23, wherein said one or more pins and said one or more through-holes are configured to provide a slidable connection.

34. The composite bone graft of claim 23, wherein a cross-section of said one or more pins comprises a shape selected from the group consisting of: round, ovoid, square, rectangular, triangular, pentagon, hexagon, and trapezoidal.

35. The composite bone graft of any one of claims 1, 2, or 11, said composite bone graft comprising a member selected form the group consisting of: a parallelepiped; a parallel block; a square block; a trapezoid wedge; a cylinder; a tapered cylinder; a flattened curved wedge, and a polyhedron.

36. A composite bone graft, comprising:

a graft unit having one or more through-holes configured to accomadate one or more pins, said graft unit comprising:

two or more bone portions layered to form said graft unit, and

one or more pins connecting bone portions of said graft unit, said composite bone graft does not comprise an adhesive.

37. The composite bone graft of claim 36, said one or more pins comprising one or more biocompatible materials selected from the group consisting of: cortical bone; stainless steel; titanium; cobalt-chromium-molybdenum alloy; a plastic of one or more members selected from the group consisting of: nylon, polycarbonate, polypropylene, polyacetal, polyethylene, and polysulfone; and one or more bioabsorbable polymers.

38. The composite bone graft of claim 37, said two or more bone portions comprising:

a first bone portion comprising one or more cortical bone portions;

a second bone portion comprising one or more cortical bone portions; and

a third bone portion comprising one or more cancellous bone portions disposed between said first bone portion and said second bone portion to form said graft unit.

39. The composite bone graft of claim 38, said one or more pins comprise one or more cortical bone pins.

40. A composite bone graft, comprising:

a graft unit having one or more through-holes configured to accomadate one or more pins, said graft unit comprising:

a first plate-like cortical bone portion;

a second plate-like cortical bone portion;

a plate-like cancellous bone portion disposed between said first plate-like cortical bone portion and said second plate-like cortical bone portion to form said graft unit, and

one or more cortical bone pins connecting bone portions of said graft unit, said composite bone graft does not comprise an adhesive.

41. A composite bone graft, comprising:

a graft unit having one or more through-holes configured to accomadate one or more pins, said graft unit comprising:

a first plate-like bone portion;

a second plate-like bone portion provided on said first plate-like bone to form said graft unit, and

one or more bone pins for holding together said graft unit, said composite bone graft does not comprise an adhesive.

42. The composite bone graft of any one of claims 36, 40 or 41, said one or more through-holes are disposed perpendicular to interfaces of bone portions of said graft unit.

43. The composite bone graft of claim 42, wherein said one or more pins and said one or more through-holes are configured to provide an interference fit for holding together said graft unit.

44. The composite bone graft of claim 43, wherein said one or more through-holes and said one or more pins are round and an inner diameter of a through-hole is smaller than a diameter of a pin, to provide an interference fit between said through-hole and said pin.

45. The composite bone graft of claim 42, wherein said one or more pins and said one or more through-holes are configured to provide a slidable connection.

46. The composite bone graft of any one of claims 36, 40, or 41, said composite bone graft comprising a member selected from the group consisting of: a parallelepiped; a parallel block; a square block; a trapezoid wedge; a cylinder; a flattened curved block, a tapered cylinder; and a polyhedron.

47. The composite bone graft of claim 46, said composite bone graft is a polyhedron.

48. The composite bone graft of claim 46, said composite bone graft further comprising: one or more textured surfaces.

49. The composite bone graft of claim 48, said one or more textured surfaces comprising: a plurality of closely spaced continuous protrusions.

50. The composite bone graft of claim 49, wherein said continuous protrusions comprise a cross-section having one or more shapes selected from the group consisting of: irregular; triangular, square, rectangular, and curved.

51. The composite bone graft of claim 49, wherein said plurality of continuous protrusions are sized to be in a range of greater than or equal to 1.5 mm in length; 0.5 to about 10.0 mm in width and 0.1 to about 5.0 mm in depth.

52. The composite bone graft of claim 51, wherein said plurality of closely spaced continuous protrusions are spaced from about 0.0 to about 3.0 mm apart.

53. A method for restoring vertical support of the posterior column, comprising implanting a composite bone graft comprising two or more distinct bone portions held together by one or more biocompatible connectors, at a site in a patient.

54. The composite bone graft of claim 36, said composite bone graft comprising a flattened curved wedge having a centrally located through-hole disposed perpendicular to interfaces of bone portions of said graft unit.

55. A composite bone graft, comprising:

a graft unit having one or more through-holes configured to accomadate one or more pins, said graft unit comprising:

two or more bone portions layered to form said graft unit,

one or more pins connecting said bone portions of said graft unit, and

a centrally located through-hole disposed perpendicular to interfaces of layered bone portions of said graft unit, said composite bone graft does not comprise an adhesive.

56. A method for making a composite bone graft for implantation into a patient, comprising:

stacking two or more parallel bone planks to form a graft unit;

providing one or more through-holes in said graft unit perpendicular to interfaces of bone planks;

connecting said two or more parallel bone planks of said graft unit with one or more pins disposed in said one or more through-holes to form a pinned graft unit; and

shaping said pinned graft unit to form said composite bone graft.

57. The composite bone graft of any one of claims 1, 2, 11, 36, 54, or 55, wherein said composite bone graft comprises one or more members selected from the group consisting of: human and animal bone.

58. The composite bone graft of any one of claims 1, 2, 11, 36, 54, or 55, wherein said composite bone graft is an allograft or xenograft.

59. The composite bone graft of any one of claims 1, 2, 11, 36, 54, or 55, wherein one or more of said bone portions comprise a demineralized bone portion.

60. The composite bone graft of claim 59, wherein said demineralized bone portion comprises a discontinuous demineralized bone portion.

61. The composite bone graft of claim 60, wherein said discontinuous demineralized bone portion comprises cancellous bone or cortical bone.

62. The composite bone graft of any one of claims 1, 2, 11, 36, 54, or 55, wherein one or more of said bone portions comprise a discontinuous bone portion.

63. The composite bone graft of claim 62, wherein said discontinuous bone portion comprises a demineralized discontinuous bone portion.

64. The composite bone graft of claim 63, wherein said demineralized discontinuous bone portion comprises cancellous or cortical bone.

65. The composite bone graft of claim 62, further comprising one or more therapeutically beneficial substances selected from the group consisting of: an osteoinductive material, an osteoconductive substance and a pharmaceutically active agent.

66. The composite bone graft of claim 65, said osteoconductive materials comprising one or more biocompatible matrix materials selected from the group consisting of: demineralized cortical bone, demineralized cancellous bone, discontinuous demineralized cortical bone, discontinuous cortical bone, collagen, cancellous bone, hydroxyapitate; polymeric matrix materials; bioglass; bioceramics; resorbable biomaterials; bioabsorbable polymers; a plastic matrix; stainless steel; titanium; and cobalt-chromium-molybdenum alloy matrix.

67. The composite bone graft of claim 65, said osteoinductive materials comprising one or more members selected from the group consisting of: autograft bone; allograft bone; demineralized cortical bone; demineralized cancellous bone; discontinuous demineralized cortical bone; collagen comprising one or more growth factors; collagen comprising demineralized bone; cancellous bone; cortical bone; and growth factors.

68. The composite bone graft of claim 65, said pharmaceutically active agent comprising one or more members selected from the group consisting of: a growth factor, a chemotherapeutic agent, an anti-inflammatory agent, and an antibiotic.

69. The composite bone graft of any one of claims 67 or 68, said growth factor comprising one or more members selected from the group consisting of: bone morphogenic protein, and transforming growth factor-β.

70. A composite bone graft, comprising:

one or more cortical bone portions layered to form a first unit;

one or more cortical bone portions layered to form a second unit;

one or more demineralized cancellous bone portions layered to form a third unit; said third unit disposed between said first unit and said second unit to form a graft unit; and

one or more biocompatible connectors for holding together said graft unit, said biocompatible connectors do not comprise an adhesive.

71. A composite bone graft, comprising:

one or more cortical bone portions layered to form a first unit;

one or more cortical bone portions layered to form a second unit;

one or more demineralized cortical bone portions layered to form a third unit; said third unit disposed between said first unit and said second unit to form a graft unit; and

one or more biocompatible connectors for holding together said graft unit, said biocompatible connectors do not comprise an adhesive.

72. The composite bone graft of claim 71, said one or more demineralized cortical bone portions comprising one or more discontinuous, demineralized cortical bone portions.

73. The composite bone graft of claim 70, said one or more demineralized cancellous bone portions comprising one or more perforated, demineralized cancellous bone portions

74. The composite bone graft of claim 72, said one or more discontinuous, demineralized cortical bone portions comprising one or more therapeutically beneficial agents.

75. The composite bone graft of claim 70, said one or more cancellous bone portions comprising one or more therapeutically beneficial agents.

76. A composite bone graft, comprising:

a first unit comprising one or more bone portions;

a second unit connected to said first unit, comprising one or mor bone portions; and

one or more biocompatible connectors for connecting said first unit and said second unit, wherein said first unit and said second unit are not in physical contact and define a void therebetween, said biocompatible connectors do not comprise an adhesive.

77. The composite bone graft of claim 76, wherein said biocompatible connectors comprise one or more mechanical connectors.

78. The composite bone graft of claim 77, said one or more mechanical connectors comprising one or more cortical bone pins.

79. The composite bone graft of claim 76, further comprising one or more therapeutically beneficial substances disposed in said void and located between and in physical contact with said first unit and said second unit.

80. The composite bone graft of claim 79, said therapeutically beneficial substances comprising one or more members selected from the group consisting of: osteoinductive materials; osteoconductive materials; and pharmaceutically active agents.

81. The composite bone graft of claim 80, said osteoconductive materials comprising one or more biocompatible matrix materials selected from the group consisting of: demineralized cortical bone, demineralized cancellous bone, discontinuous demineralized cortical bone, discontinuous cortical bone, collagen, cancellous bone, hydroxyapitate; polymeric matrix materials; bioglass; bioceramics; resorbable Biomaterials; bioabsorbable polymers; a plastic matrix; stainless steel; titanium; and cobalt-chromium-molybdenum alloy matrix.

82. The composite bone graft of claim 80, said osteoinductive materials comprising one or more members selected from the group consisting of: autograft bone; allograft bone; demineralized cortical bone; demineralized cancellous bone; discontinuous demineralized cortical bone; collagen comprising one or more growth factors; collagen comprising demineralized bone; cancellous bone; cortical bone; and growth factors.

83. The composite bone graft of claim 80, said pharmaceutically active agent comprising one or more members selected from the group consisting of: a growth factor, a chemotherapeutic agent, an anti-inflammatory agent, and an antibiotic.

84. The composite bone graft of any one of claims 82 or 83, said growth factor comprising one or more members selected from the group consisting of: bone morphogenic protein, and transforming growth factor-β.

85. The composite bone graft of claim 80, comprising said one or more osteoinductive substances and one or more osteoconductive substances, wherein said one or more osteoinductive substances are disposed within a matrix of said one or more osteoconductive substances.

86. The composite bone graft of any one of claims 2 or 3, said bone portions comprising two or more cortical bone portions layered to form a graft unit.

87. The composite bone graft of claim 86, said cortical bone portions comprising complementary patterns provided thereon to enable an interlocking fit between adjacent cortical bone portions.

88. The composite bone graft of claim 86, further comprising: one or more channels selected from the group consisting of: a vertically disposed channel, a horizontally disposed channel, and a randomly disposed channel.

89. The composite bone graft of claim 88, said one or more channels further comprising: one or more therapeutically beneficial substances.

90. A composite bone graft, comprising: two or more distinct interlocking cortical bone portions.

91. The composite bone graft of claim 90, said two or more distinct interlocking bone portions are each provided with complementary discrete or continuous interlocking patterns.

92. A composite bone graft, comprising: two or more distinct adjacent bone portions where adjacent bone portions are configured to interlock with each other.

93. A composite bone graft, comprising: two or more distinct adjacent bone portions where adjacent bone portions are configured to interlock with each other, and one or more locking pins partially or entirely traversing a dimension of said composite bone graft.

94. The composite bone graft of claim 93, wherein said dimension comprises length, width, or height.

95. A composite bone graft, comprising: two or more distinct adjacent bone portions where adjacent bone portions are configured to interlock with each other to form an interlocked graft unit, said interlocked graft unit is self-locking.

96. A composite bone graft, comprising: two or more distinct adjacent bone portions, said distinct adjacent bone portions comprising complementary peg-like protrusions and corresponding depressions, said protrusions and depressions interlock to provide an interlocking fit between said adjacent bone portions.

97. The composite bone graft of claim 96, further comprising: one or more locking pins partially or entirely traversing a dimension of said composite bone graft.

98. The composite bone graft of anyone of claims 92, 93, 95, or 96, said two or more distinct adjacent bone portions comprise one or more members selected from the

group consisting of: cortical bone and cancellous bone.

99. The composite bone graft of claim 98, said two or more distinct adjacent interlocking bone portions comprise cortical bone.

100. A composite bone graft, consisting essentially of: two or more distinct adjacent bone portions where adjacent bone portions are configured to interlock with each other.

101. A composite bone graft, consisting essentially of: two or more distinct adjacent bone portions, said distinct adjacent bone portions comprising complementary peg-like protrusions and corresponding depressions, said protrusions and depressions interlock to provide an interlocking fit between said adjacent bone portions.

102. A composite bone graft, consisting essentially of: two or more distinct adjacent bone portions, said distinct adjacent bone portions comprising complementary peg-like protrusions and corresponding depressions, said protrusions and depressions interlock to provide an interlocking fit between said adjacent bone portions; and one or more locking pins partially or entirely traversing a dimension of said composite bone graft.

103. A composite bone graft, consisting essentially of: two or more distinct adjacent bone portions where adjacent bone portions are configured to interlock with each other, and one or more locking pins partially or entirely traversing a dimension of said composite bone graft.

104. The method of claim 57, said two or more parallel bone planks comprising two or more parallel bone planks configured to interlock with each other.

105. The composite bone graft of claim 90, said two or more distinct interlocking bone portions are each provided with complementary discrete interlocking patterns.

106. The composite bone graft of claim 105, said discrete interlocking patterns comprising: peg-like protrusions provided on a bone portion and corresponding depressions provided on an adjacent bone portion, said protrusions and depressions interlock to provide an interlocking fit between said adjacent bone portions.

107. A composite bone graft, comprising: two or more distinct adjacent bone portions where adjacent bone portions are configured to interlock with each other to form an interlocked graft unit, and one or more locking pins traversing a dimension of said composite bone graft, to lock said interlocked graft unit.

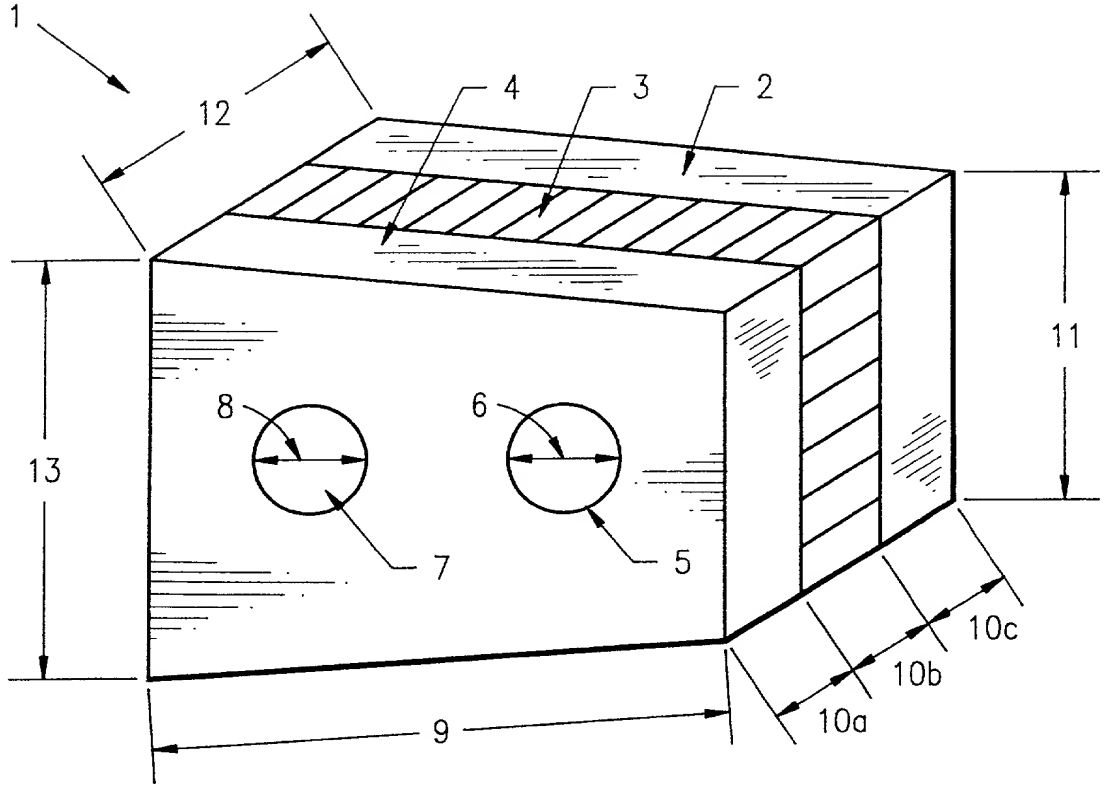
108. A composite bone graft, comprising: two or more distinct interlocking bone portions, said interlocking bone portions are self-locking.

109. A composite bone graft, comprising: two or more distinct interlocking bone portions, and one or more locking pins to lock said interlocking bone portions.

ABSTRACT OF THE DISCLOSURE

The invention is directed to a composite bone graft for implantation in a patient, and methods of making and using the composite bone graft, along with methods for treating patients by implanting the composite bone graft at a site in a patient. The composite bone graft includes two or more connected, discrete, bone portions, and includes one or more biocompatible connectors which hold together the discrete bone portions to form the composite bone graft. The composite bone graft may include one or more textured bone surfaces. The textured surface preferably includes a plurality of closely spaced protrusions, preferably closely spaced continuous protrusions. The composite bone graft is useful for repairing bone defects caused by congenital anomaly, disease, or trauma, in a patient, for example, for restoring vertical support of the anterior and/or posterior column. Implantation of the composite bone graft results in improved graft stability and osteoinductivity, without a decrease in mechanical strength. The composite bone graft does not shift, extrude or rotate, after implantation. The present composite bone graft can be appropriately sized for any application and can be used to replace traditional non-bone prosthetic implants.

FIG. 1



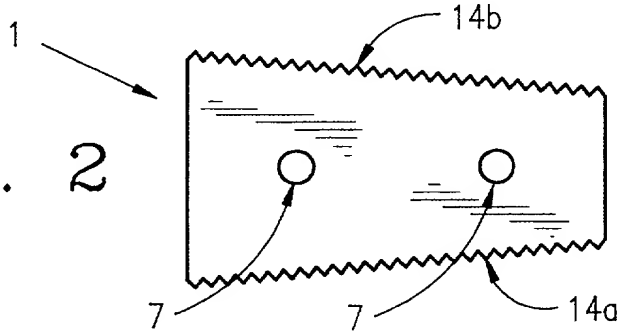


FIG. 2

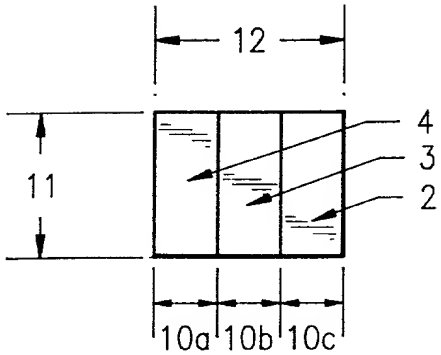


FIG. 3

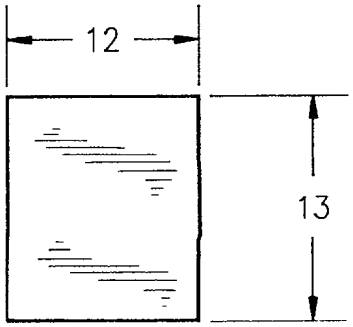


FIG. 4

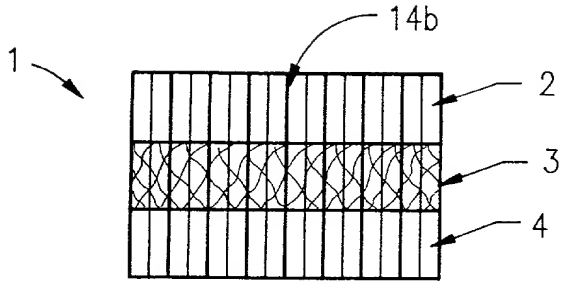


FIG. 5

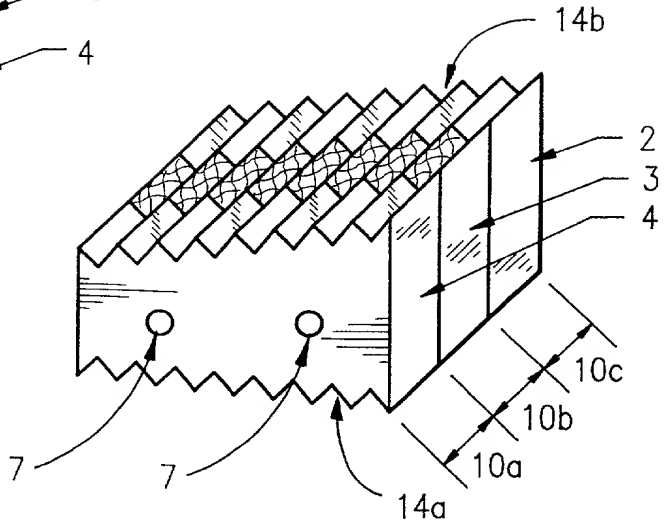


FIG. 6

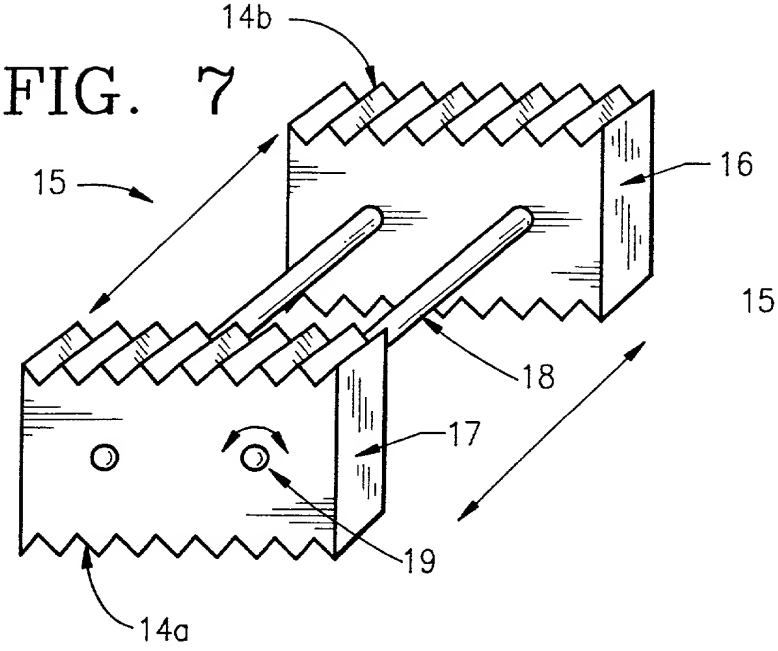


FIG. 7

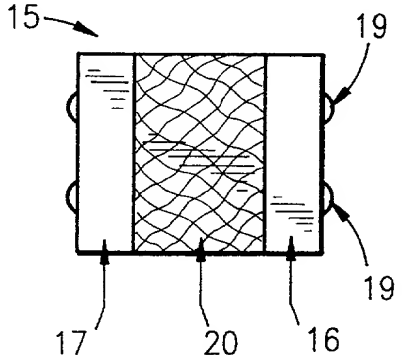


FIG. 8

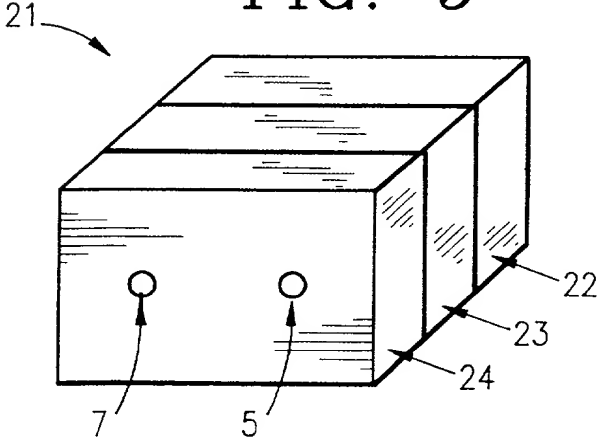


FIG. 9

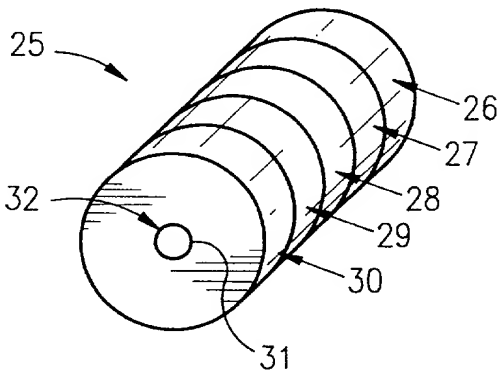


FIG. 10

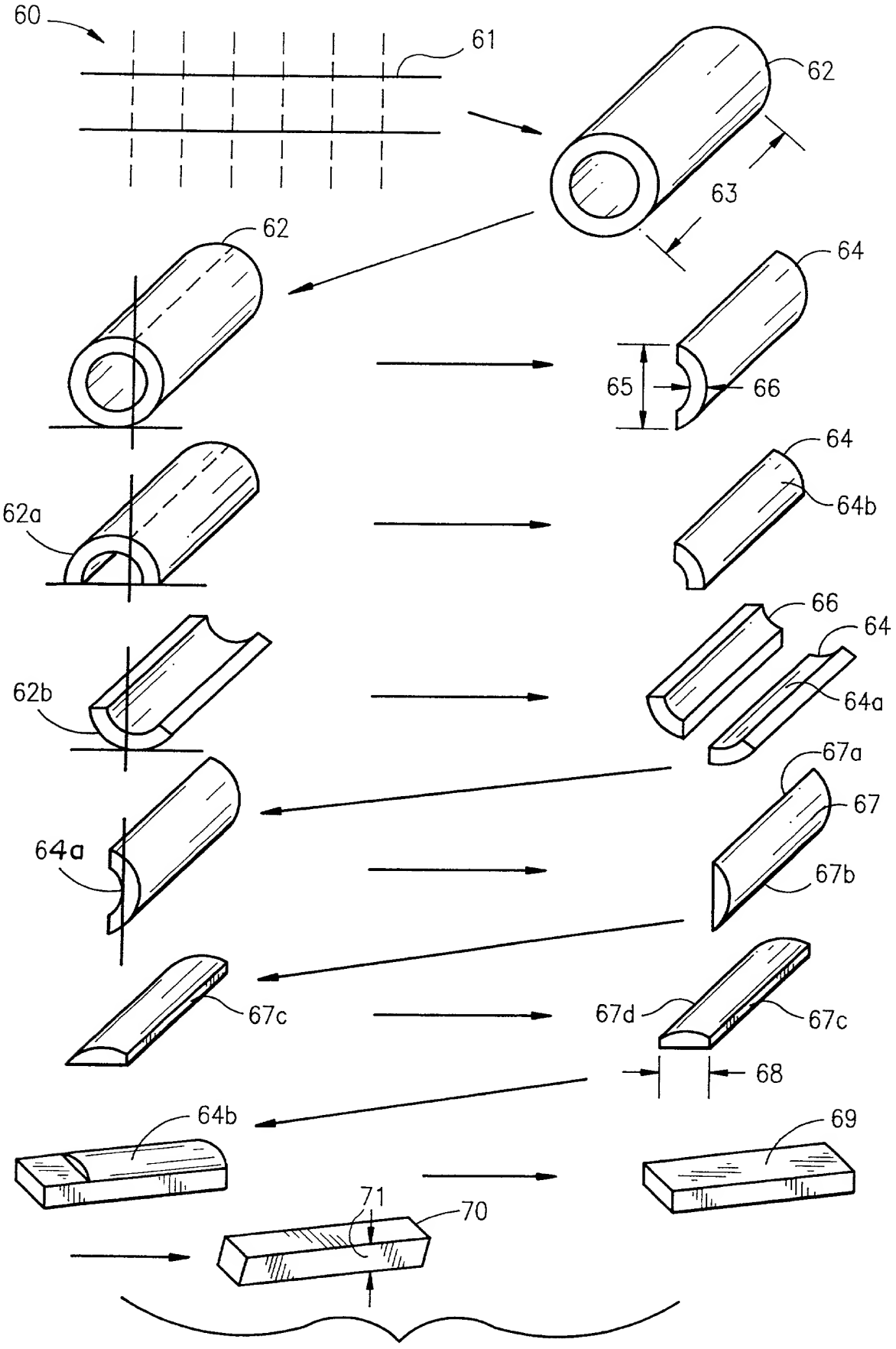

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FIG. 11A

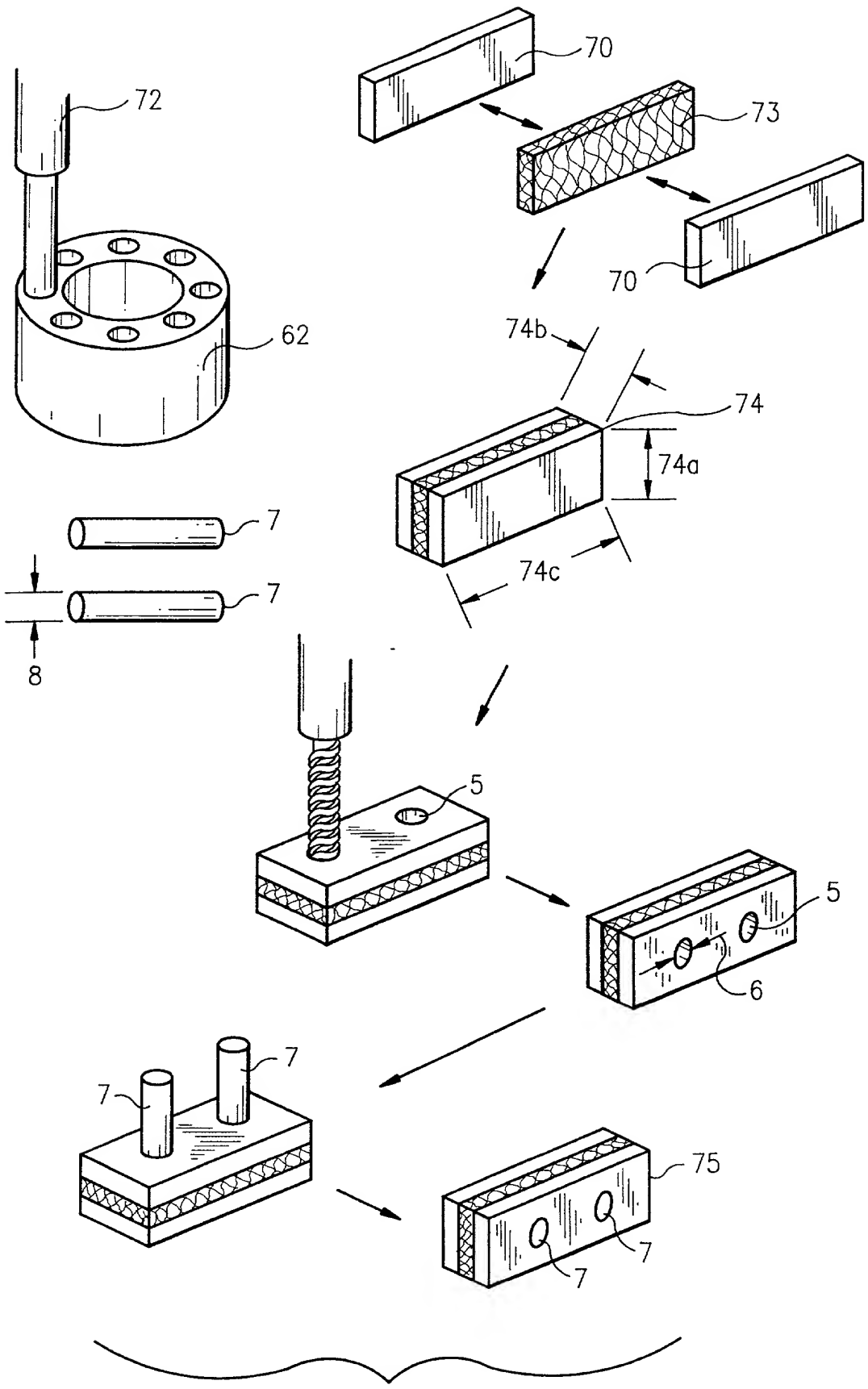

FIG. 11B

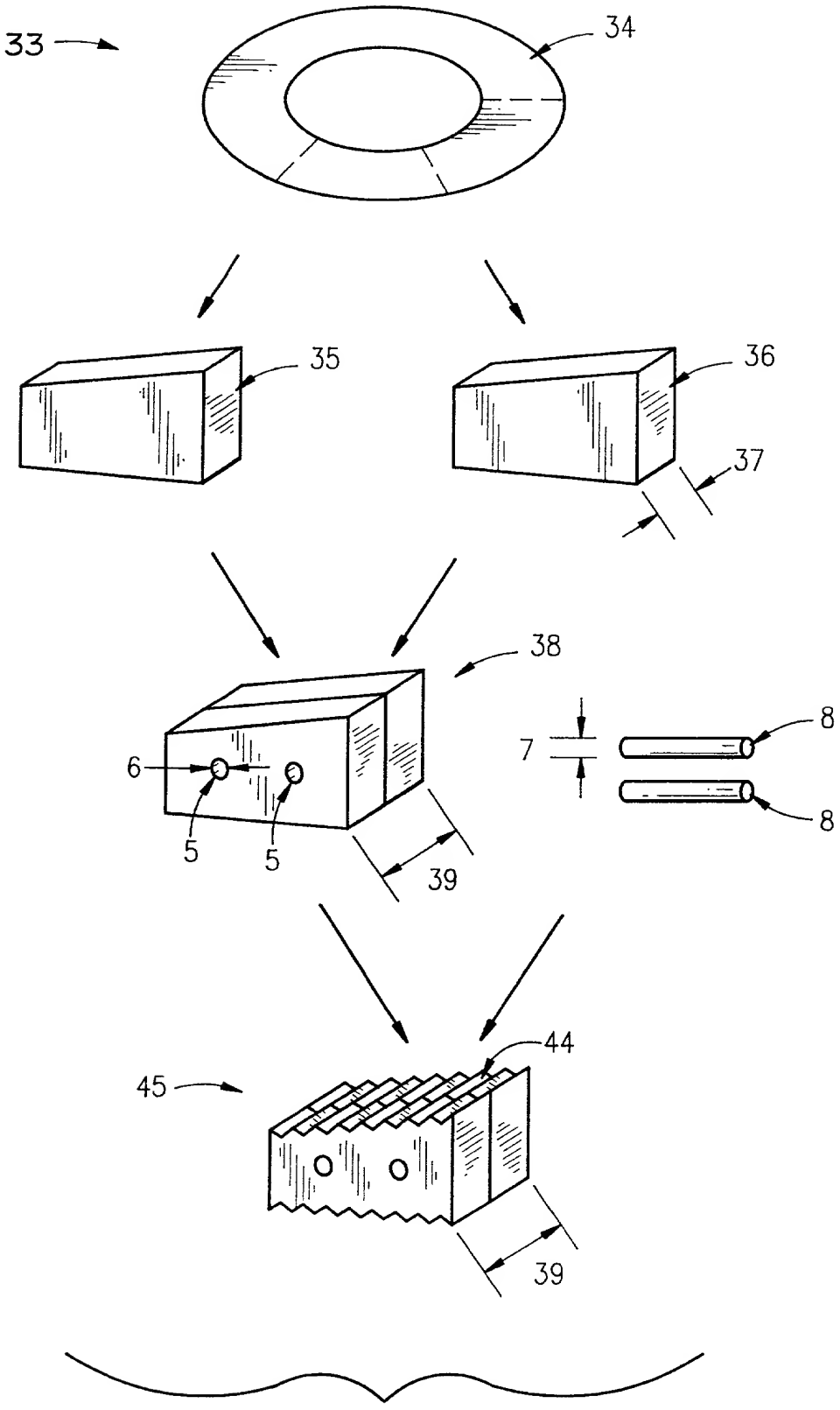

FIG. 12

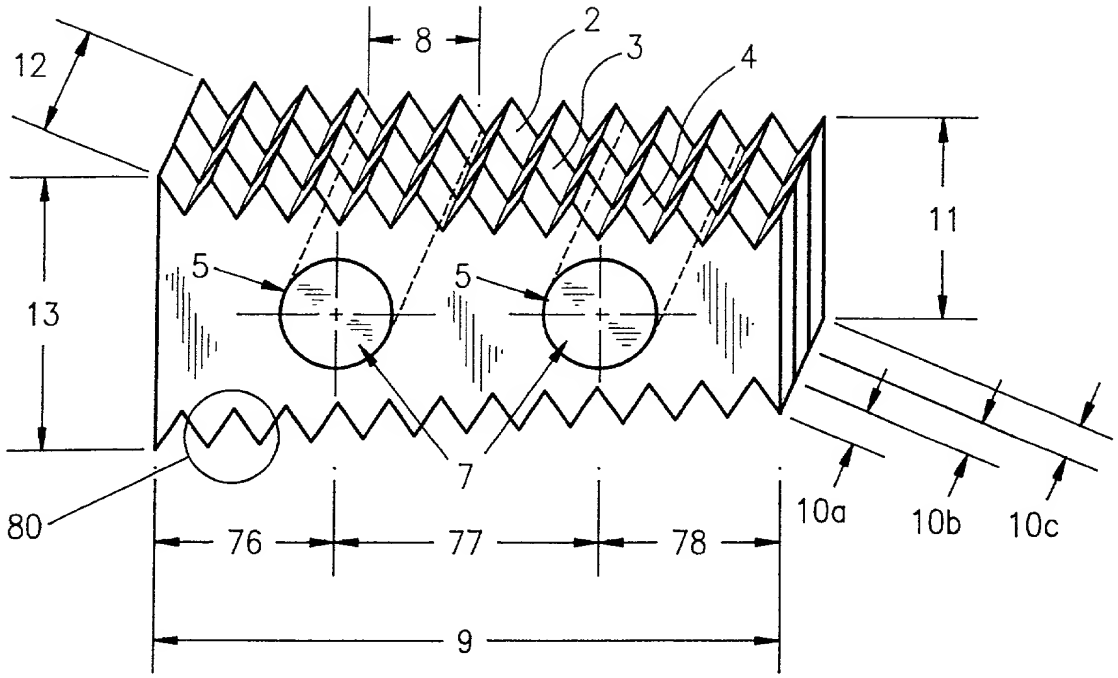

FIG. 13A

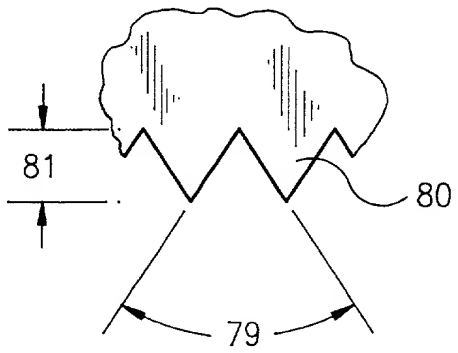

FIG. 13B

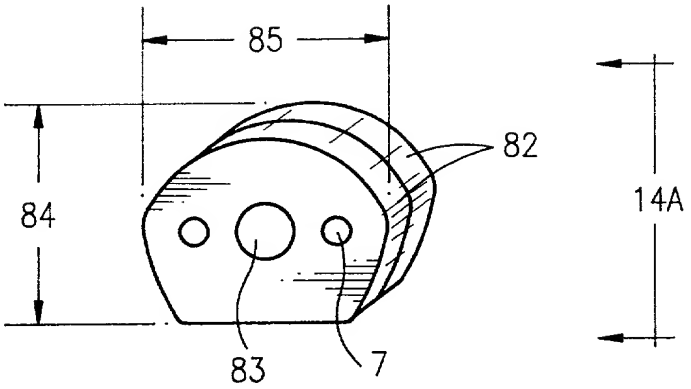

FIG. 14A

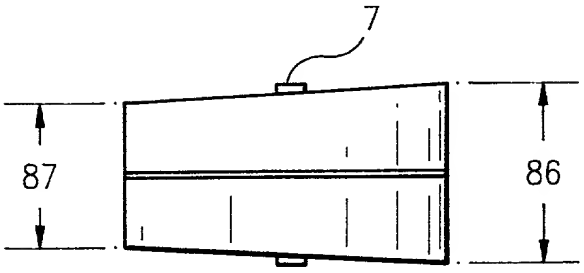

FIG. 14B

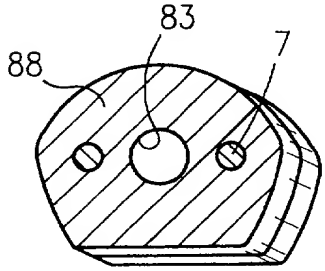

FIG. 14C

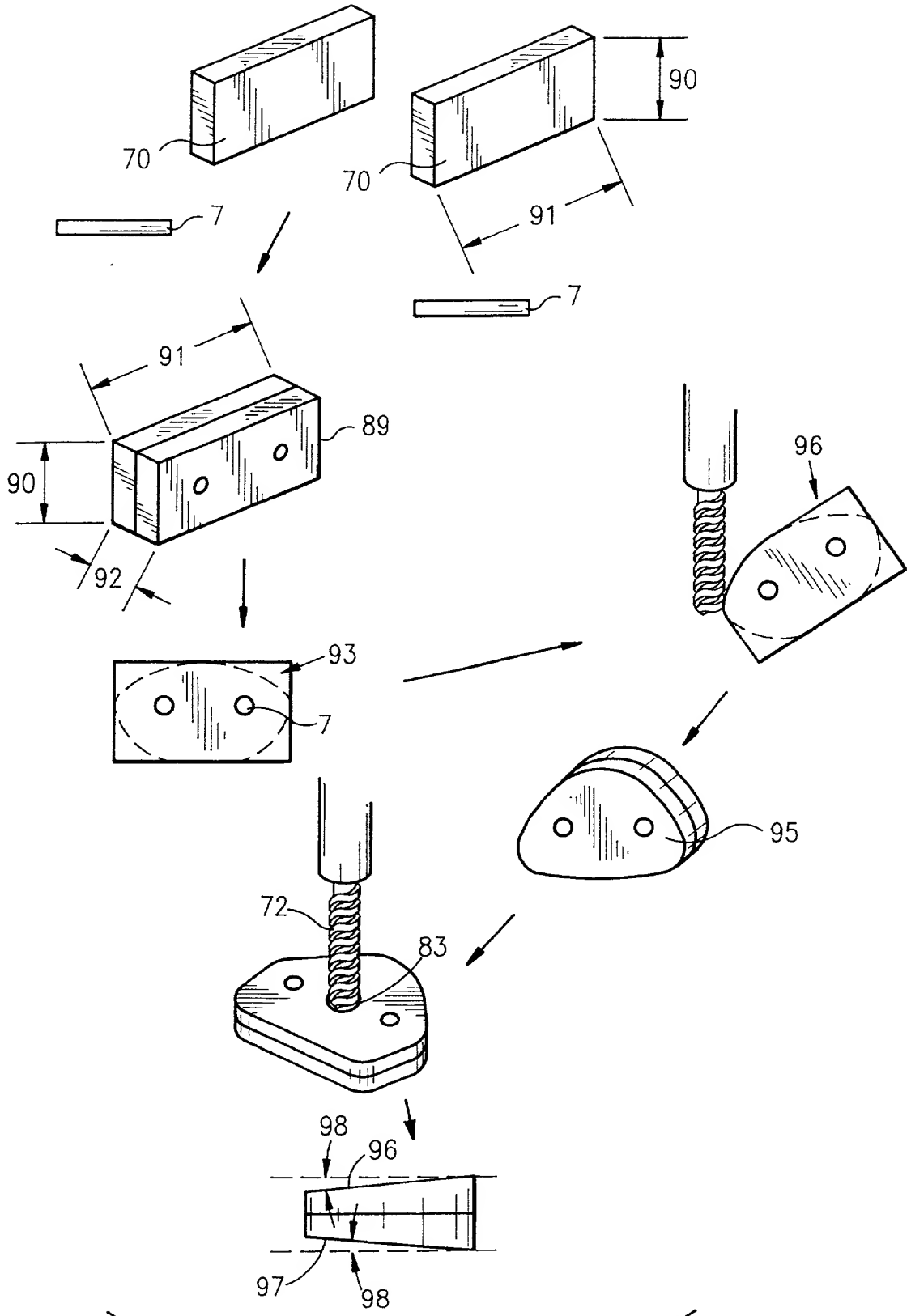

FIG. 15

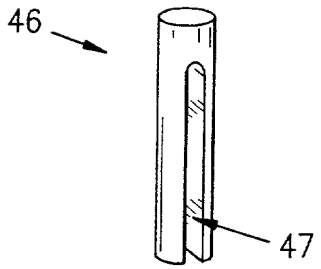

FIG. 16

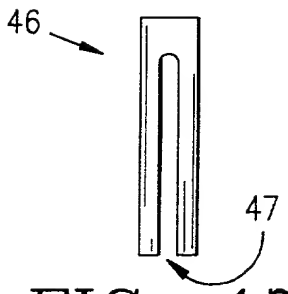

FIG. 17

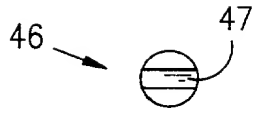

FIG. 18

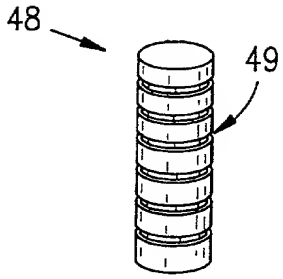

FIG. 19

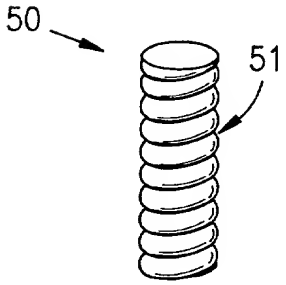

FIG. 20

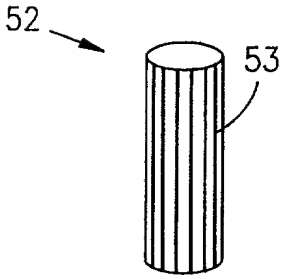

FIG. 21

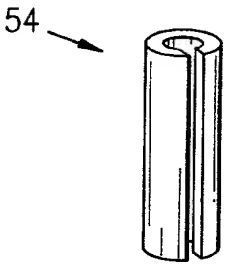

FIG. 22

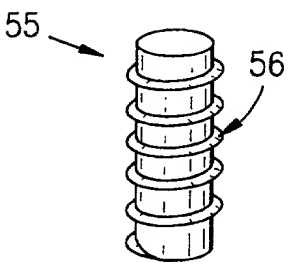

FIG. 23

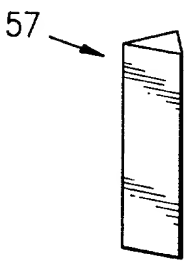

FIG. 24

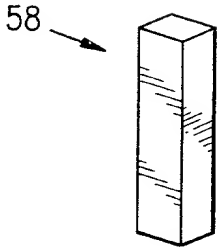

FIG. 25

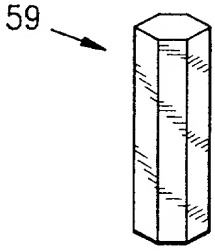

FIG. 26

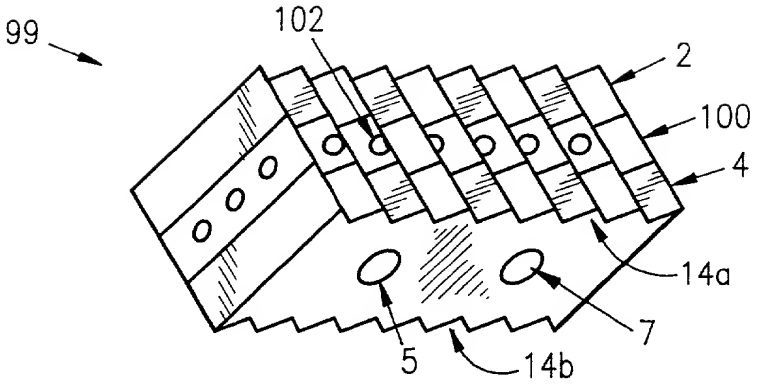

FIG. 27

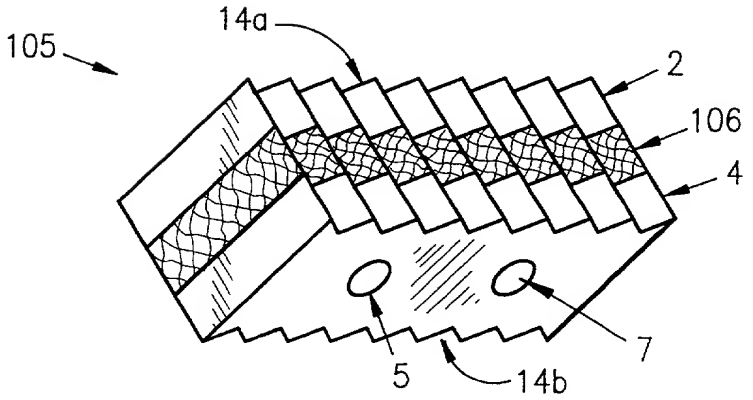

FIG. 28

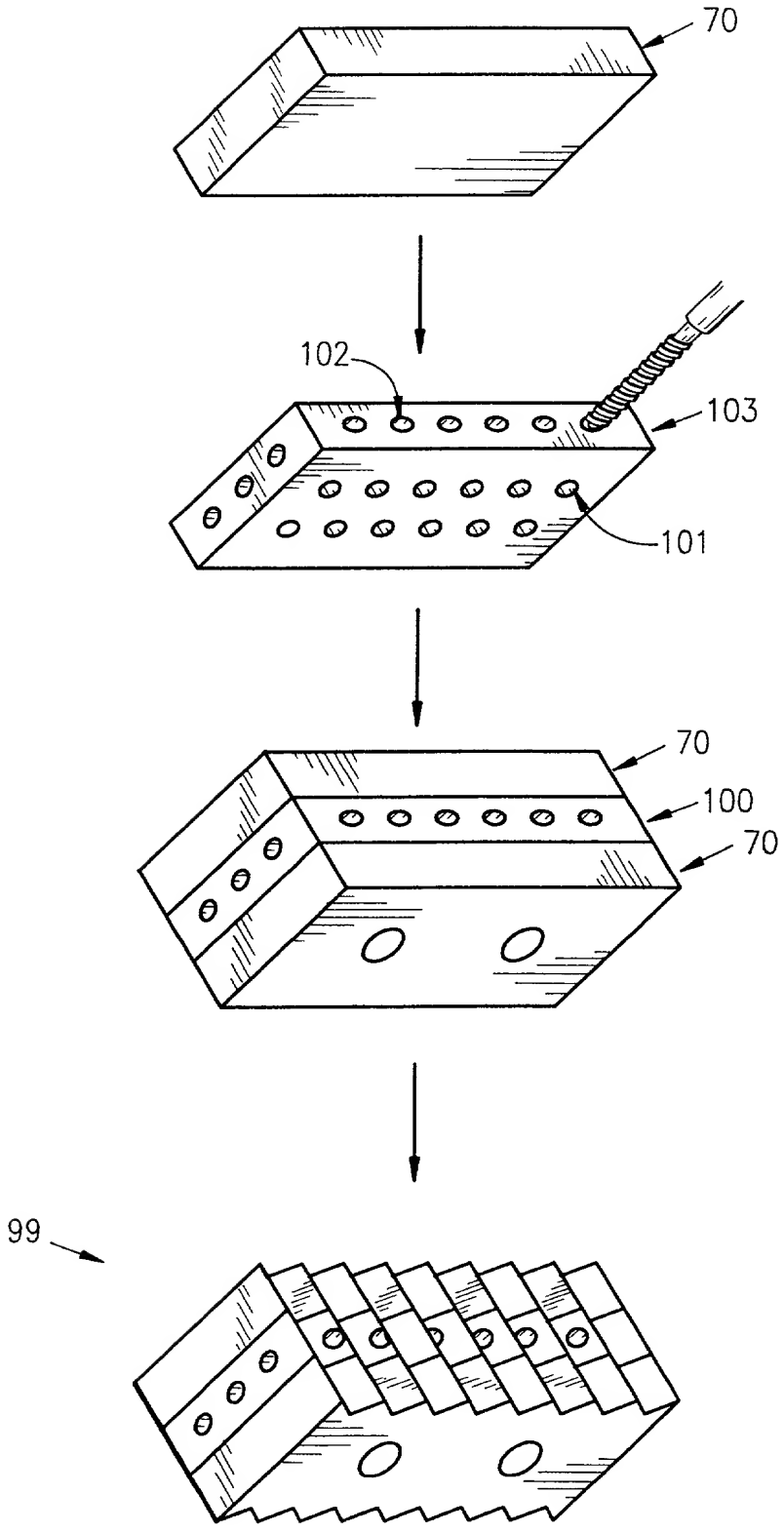

FIG. 29

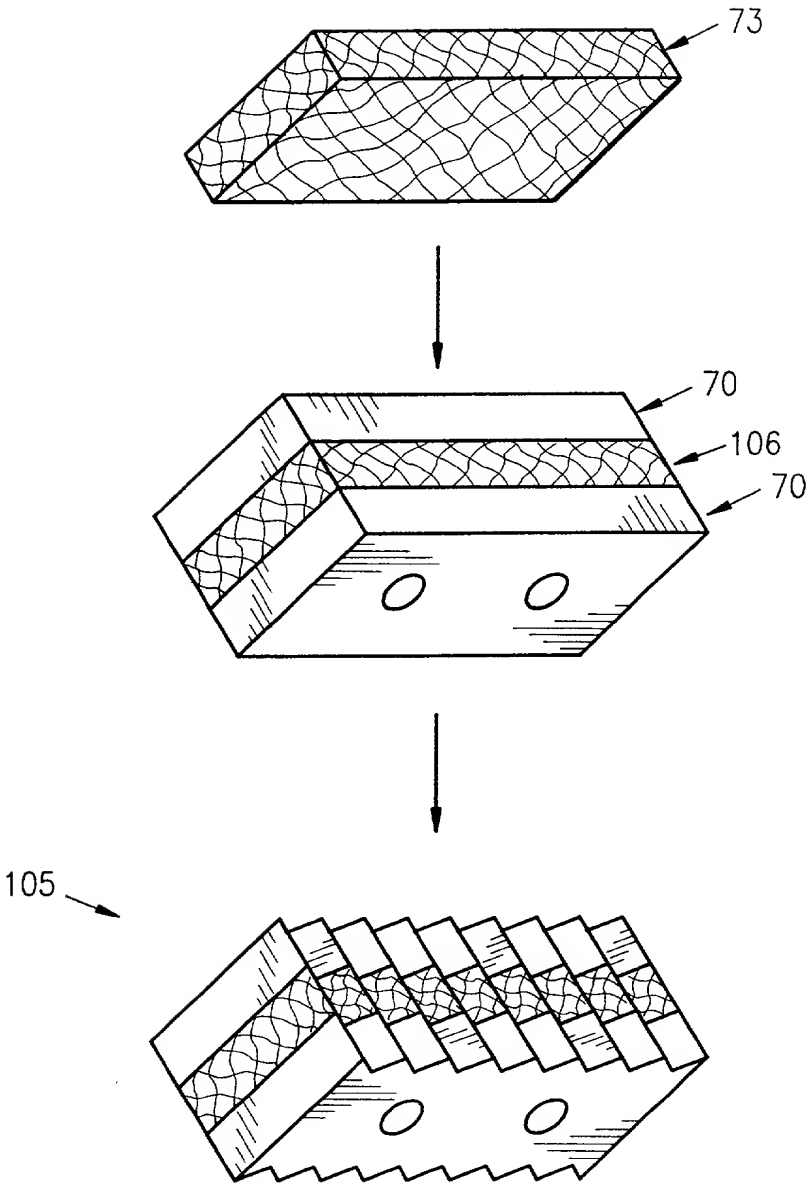

FIG. 30

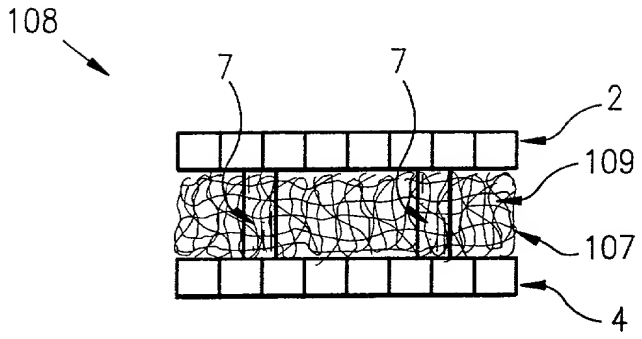

FIG. 31A

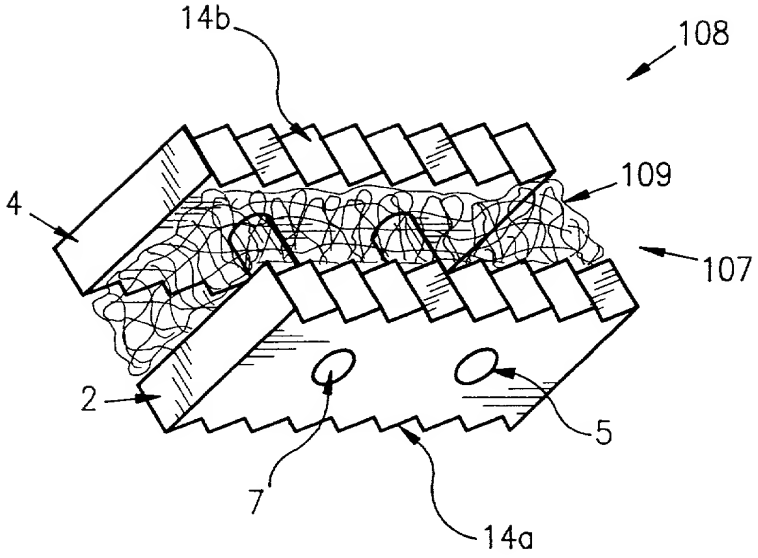

FIG. 31B

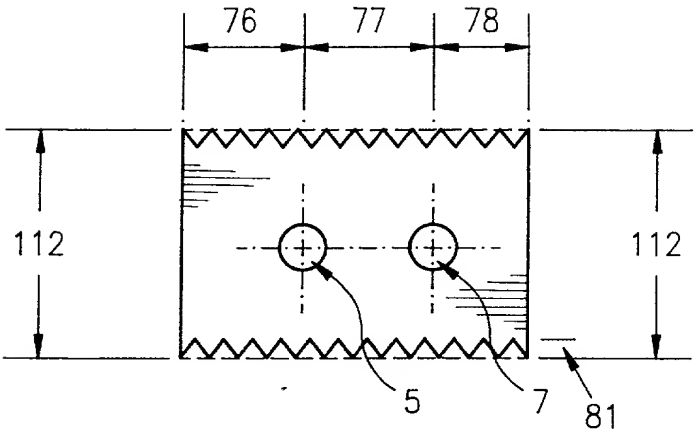

FIG. 32A

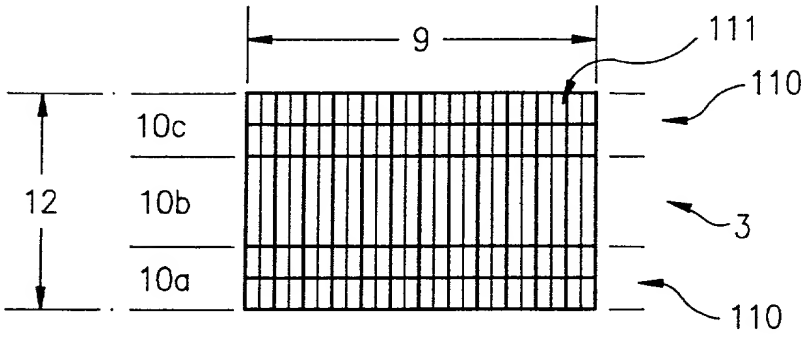

FIG. 32B

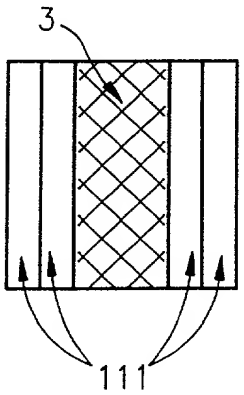

FIG. 32C

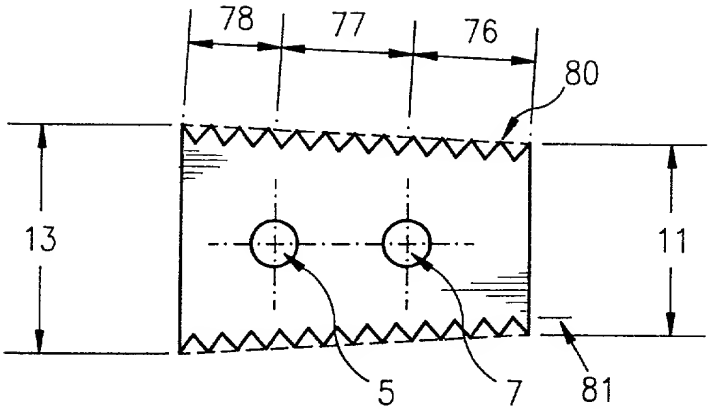

FIG. 33A

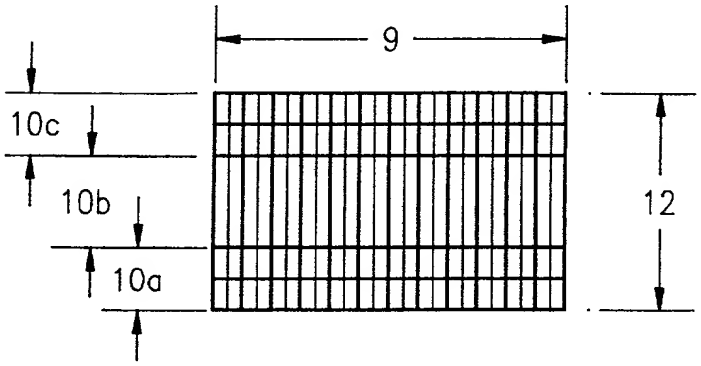

FIG. 33B

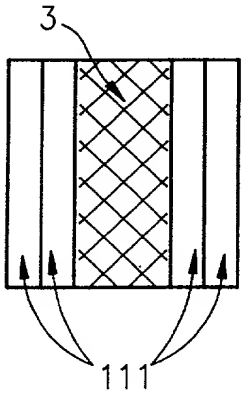

FIG. 33C

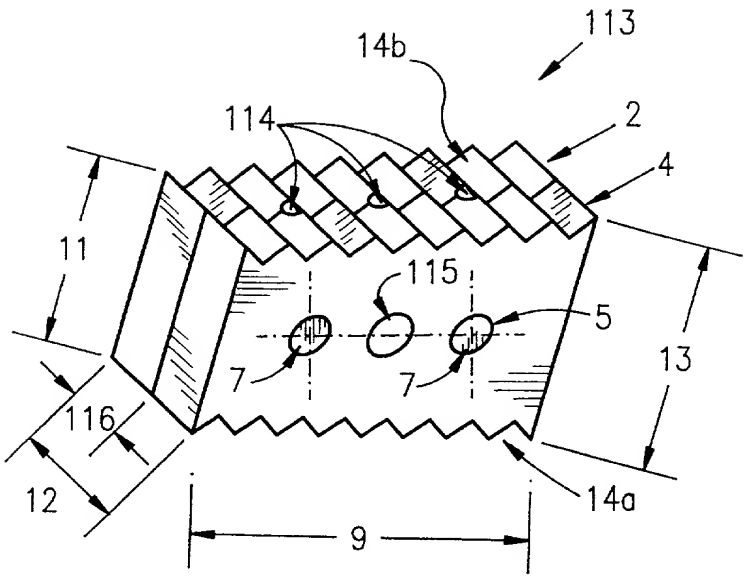

FIG. 34

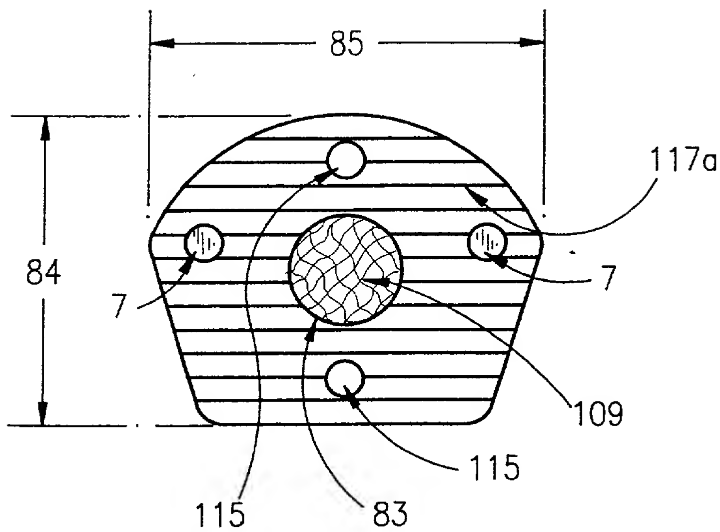

FIG. 35A

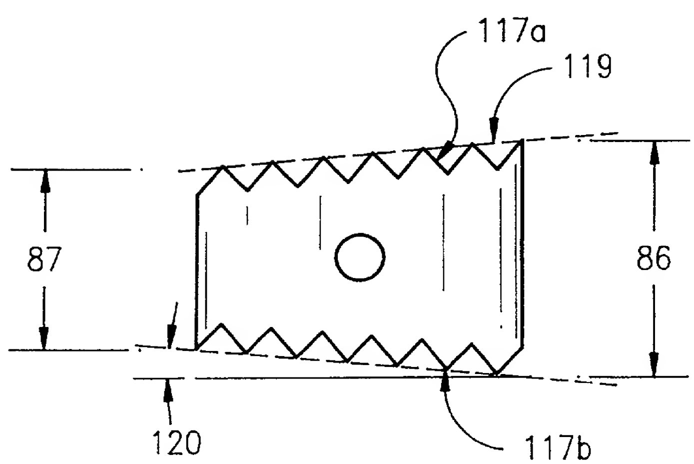

FIG. 35B

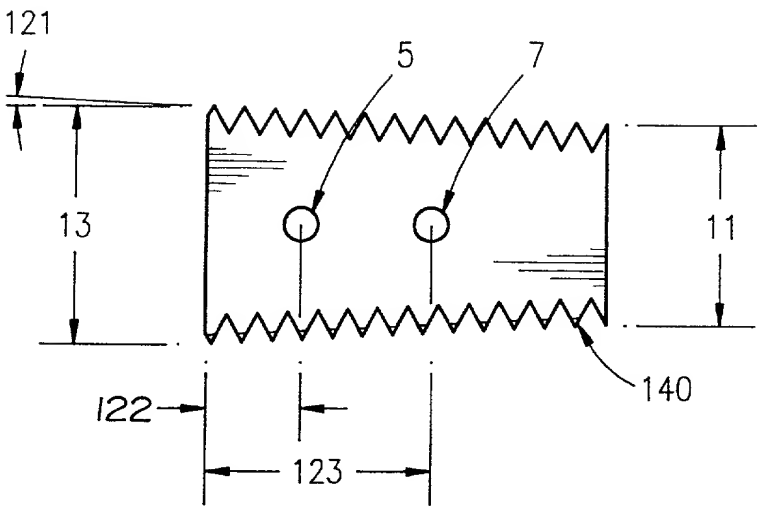

FIG. 36A

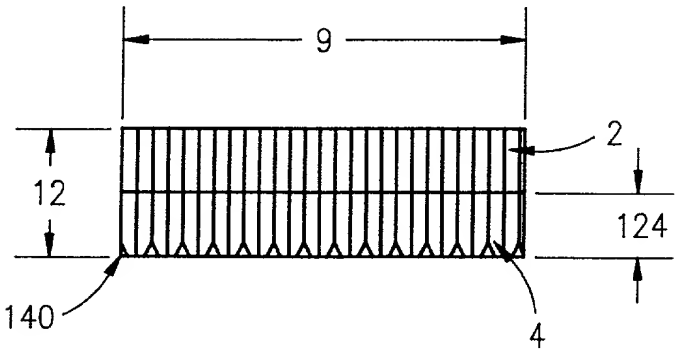

FIG. 36B

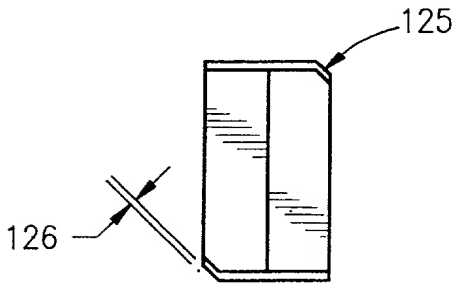

FIG. 36C

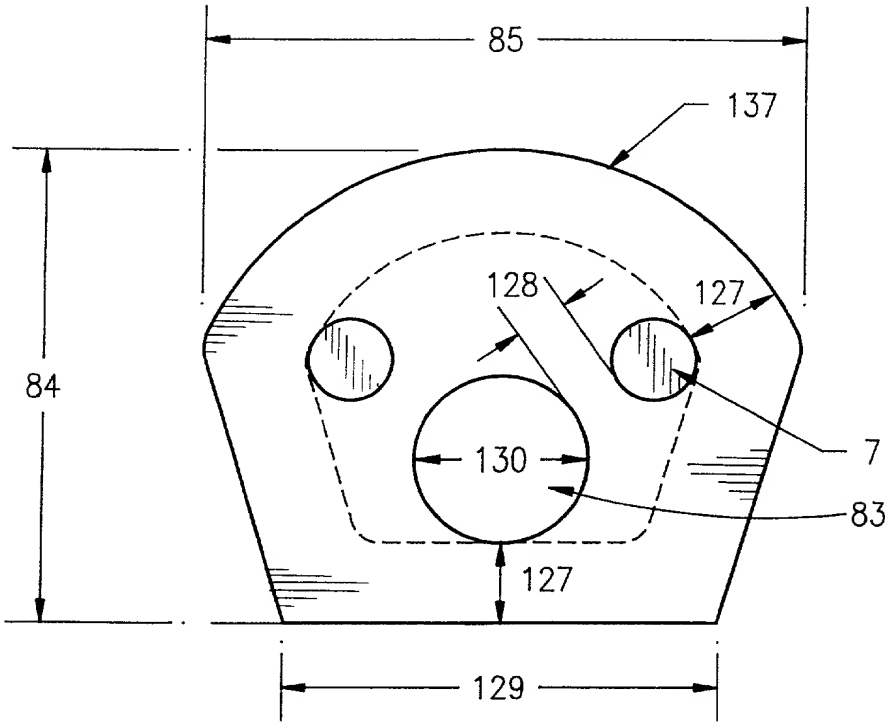
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FIG. 37

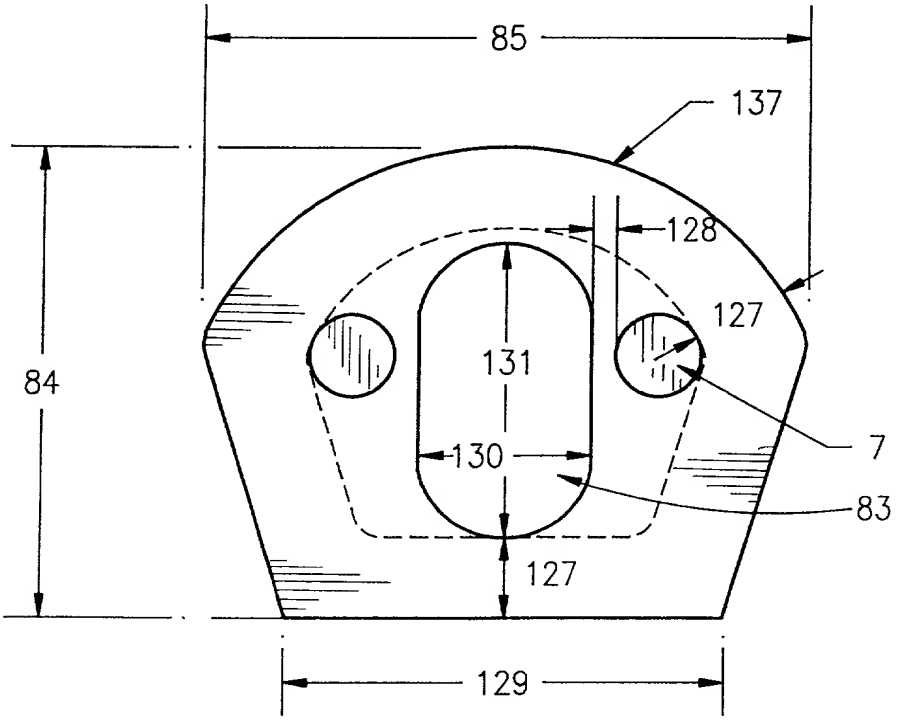
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FIG. 38

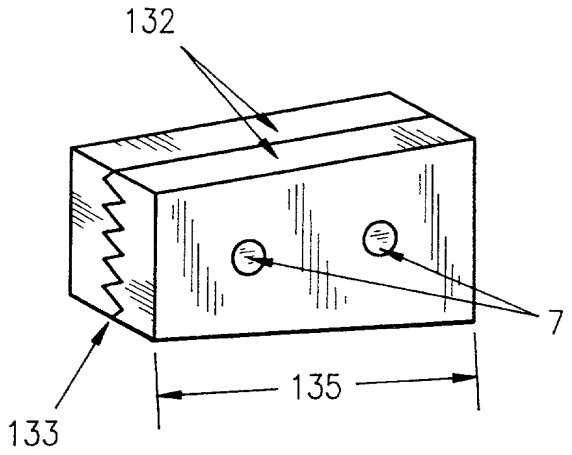

FIG. 39

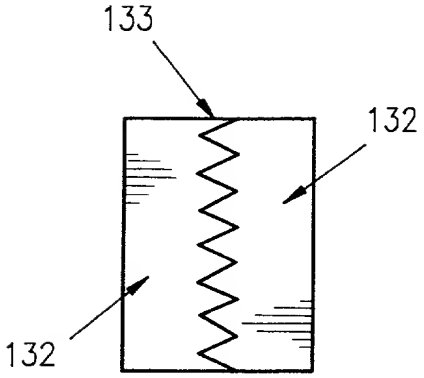

FIG. 40A

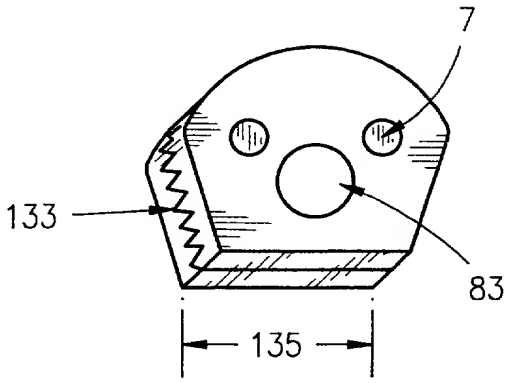

FIG. 40B

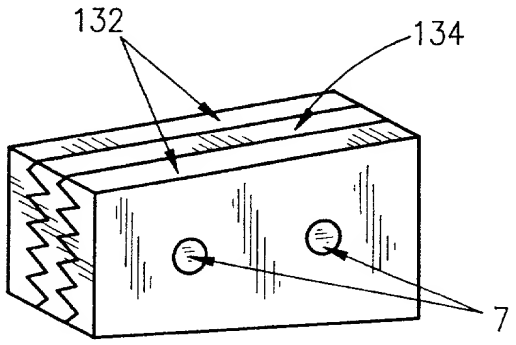

FIG. 41

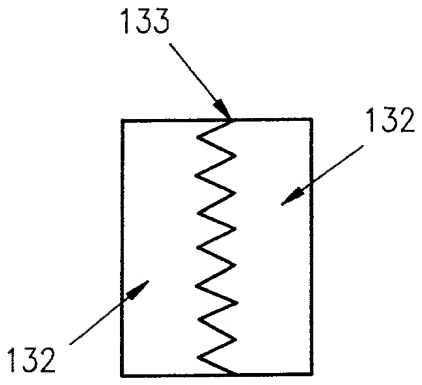

FIG. 42A

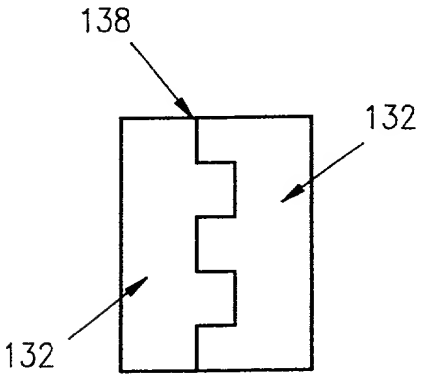

FIG. 42B

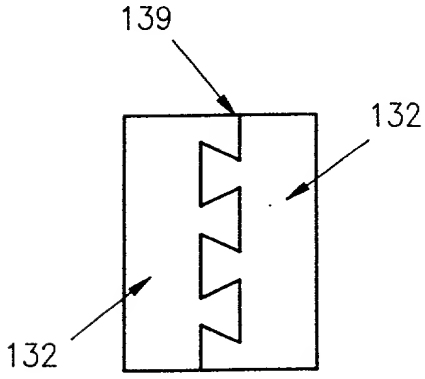

FIG. 42C

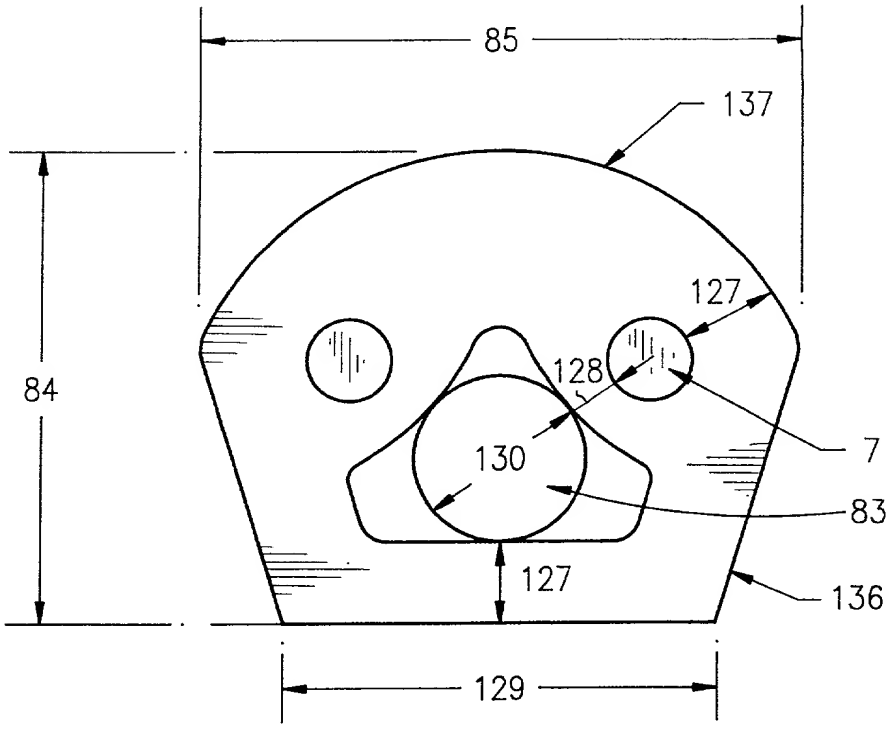
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FIG. 43

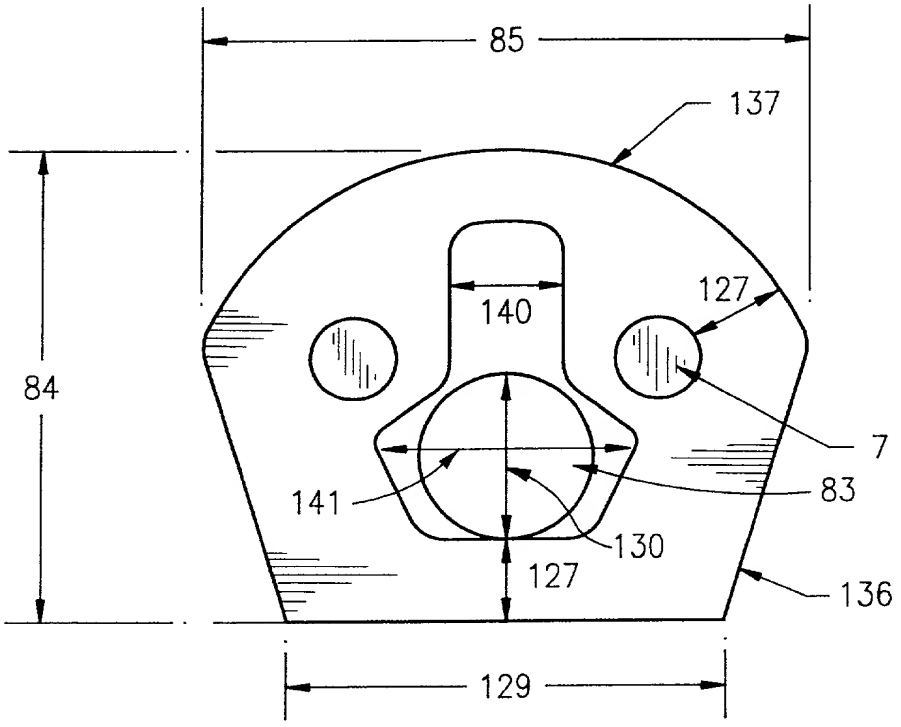
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FIG. 44

Docket No.
LN.014C2

Declaration and Power of Attorney For Patent Application

English Language Declaration

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name,

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled

COMPOSITE BONE GRAFT, METHOD OF MAKING AND USING SAME

the specification of which

(check one)

☒ is attached hereto.

☐ was filed on _____ as United States Application No. or PCT International Application Number _____

and was amended on _____

(if applicable)

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose to the United States Patent and Trademark Office all information known to me to be material to patentability as defined in Title 37, Code of Federal Regulations, Section 1.56.

I hereby claim foreign priority benefits under Title 35, United States Code, Section 119(a)-(d) or Section 365(b) of any foreign application(s) for patent or inventor's certificate, or Section 365(a) of any PCT International application which designated at least one country other than the United States, listed below and have also identified below, by checking the box, any foreign application for patent or inventor's certificate or PCT International application having a filing date before that of the application on which priority is claimed.

Prior Foreign Application(s)			Priority Not Claimed
_____ (Number)	_____ (Country)	_____ (Day/Month/Year Filed)	☐
_____ (Number)	_____ (Country)	_____ (Day/Month/Year Filed)	☐
_____ (Number)	_____ (Country)	_____ (Day/Month/Year Filed)	☐

I hereby claim the benefit under 35 U.S.C. Section 119(e) of any United States provisional application(s) listed below:

(Application Serial No.)	(Filing Date)
(Application Serial No.)	(Filing Date)
(Application Serial No.)	(Filing Date)

I hereby claim the benefit under 35 U. S. C. Section 120 of any United States application(s), or Section 365(c) of any PCT International application designating the United States, listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States or PCT International application in the manner provided by the first paragraph of 35 U.S.C. Section 112. I acknowledge the duty to disclose to the United States Patent and Trademark Office all information known to me to be material to patentability as defined in Title 37, C. F. R., Section 1.56 which became available between the filing date of the prior application and the national or PCT International filing date of this application:

09/225,299	**January 5, 1999**	**Pending**
(Application Serial No.)	(Filing Date)	(Status) (patented, pending, abandoned)
09/286,975	**April 6, 1999**	**Pending**
(Application Serial No.)	(Filing Date)	(Status) (patented, pending, abandoned)
(Application Serial No.)	(Filing Date)	(Status) (patented, pending, abandoned)

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

POWER OF ATTORNEY: As a named inventor, I hereby appoint the following attorney(s) and/or agent(s) to prosecute this application and transact all business in the Patent and Trademark Office connected therewith. *(list name and registration number)*

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